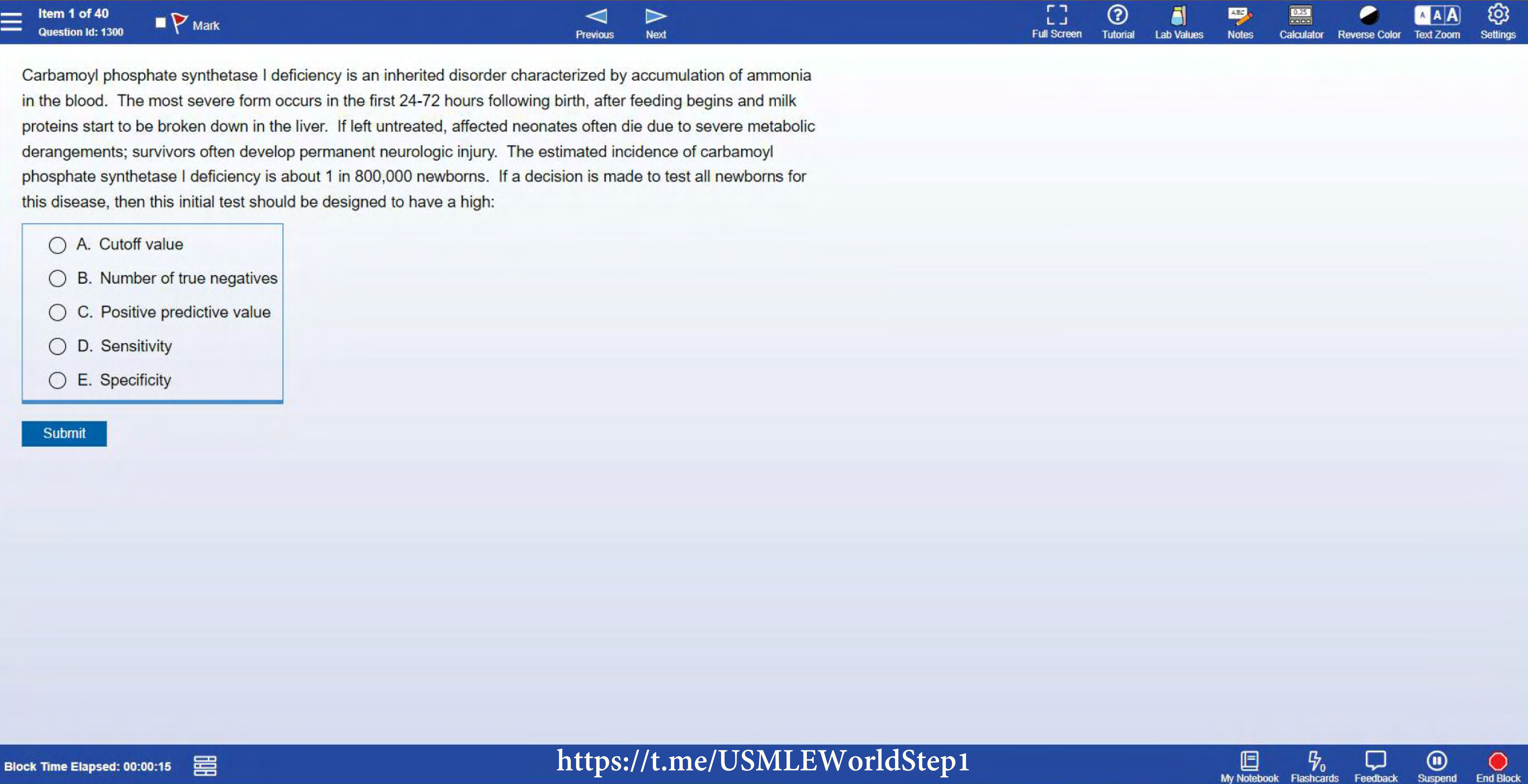
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Item 1 of 40
Question Id: 1300

Carbamoyl phosphate synthetase I deficiency is an inherited disorder characterized by accumulation of ammonia in the blood. The most severe form occurs in the first 24-72 hours following birth, after feeding begins and milk proteins start to be broken down in the liver. If left untreated, affected neonates often die due to severe metabolic derangements; survivors often develop permanent neurologic injury. The estimated incidence of carbamoyl phosphate synthetase I deficiency is about 1 in 800,000 newborns. If a decision is made to test all newborns for this disease, then this initial test should be designed to have a high:

○ A. Cutoff value
○ B. Number of true negatives
○ C. Positive predictive value
○ D. Sensitivity
○ E. Specificity

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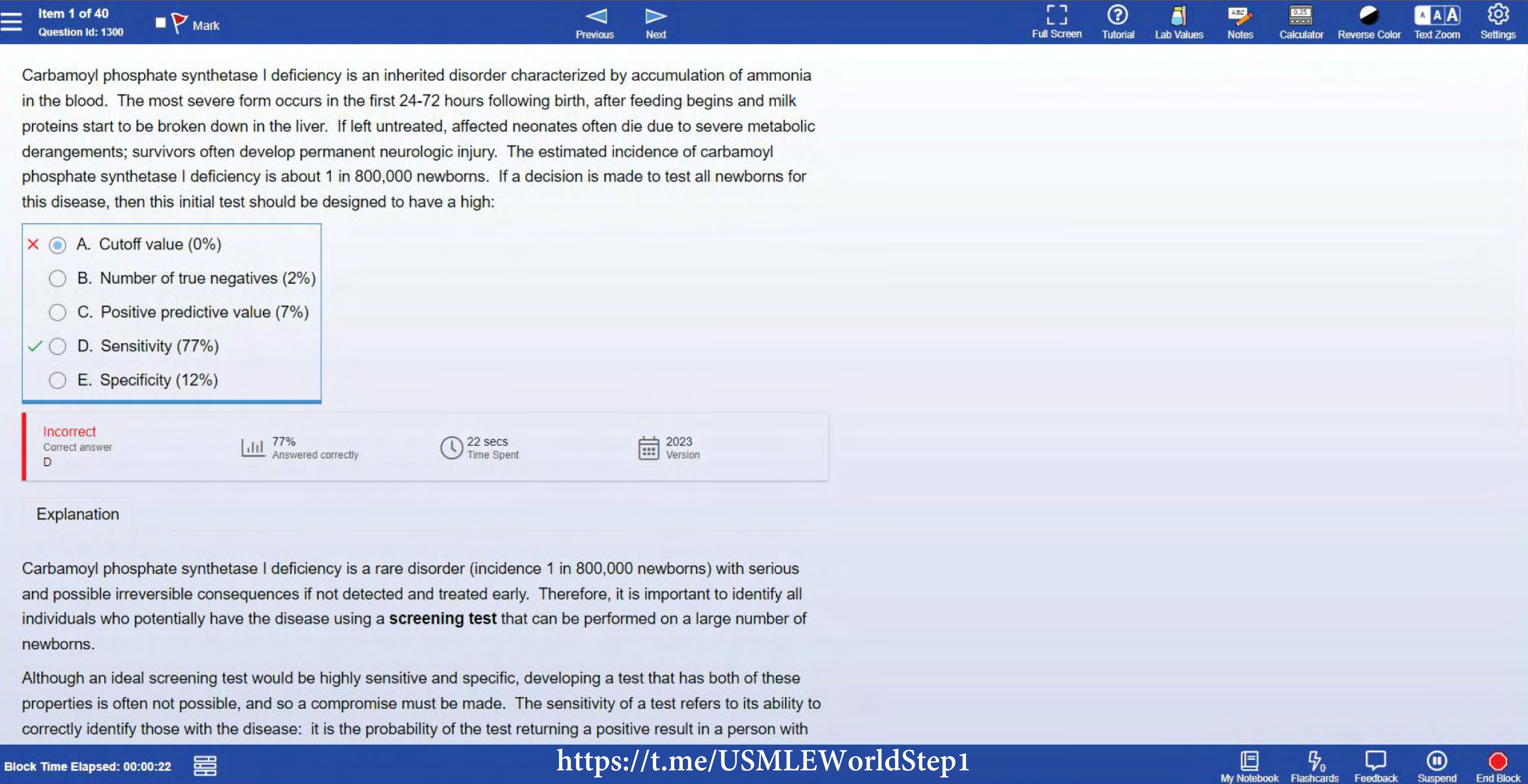
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Carbamoyl phosphate synthetase I deficiency is an inherited disorder characterized by accumulation of ammonia in the blood. The most severe form occurs in the first 24-72 hours following birth, after feeding begins and milk proteins start to be broken down in the liver. If left untreated, affected neonates often die due to severe metabolic derangements; survivors often develop permanent neurologic injury. The estimated incidence of carbamoyl phosphate synthetase I deficiency is about 1 in 800,000 newborns. If a decision is made to test all newborns for this disease, then this initial test should be designed to have a high:

✗ ● A. Cutoff value (0%)
○ B. Number of true negatives (2%)
○ C. Positive predictive value (7%)
✓ ○ D. Sensitivity (77%)
○ E. Specificity (12%)

Incorrect
Correct answer
D

77%
Answered correctly

22 secs
Time Spent

2023
Version

Explanation

Carbamoyl phosphate synthetase I deficiency is a rare disorder (incidence 1 in 800,000 newborns) with serious and possible irreversible consequences if not detected and treated early. Therefore, it is important to identify all individuals who potentially have the disease using a **screening test** that can be performed on a large number of newborns.

Although an ideal screening test would be highly sensitive and specific, developing a test that has both of these properties is often not possible, and so a compromise must be made. The sensitivity of a test refers to its ability to correctly identify those with the disease: it is the probability of the test returning a positive result in a person with

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Carbamoyl phosphate synthetase I deficiency is a rare disorder (incidence 1 in 800,000 newborns) with serious and possible irreversible consequences if not detected and treated early. Therefore, it is important to identify all individuals who potentially have the disease using a **screening test** that can be performed on a large number of newborns.

Although an ideal screening test would be highly sensitive and specific, developing a test that has both of these properties is often not possible, and so a compromise must be made. The sensitivity of a test refers to its ability to correctly identify those with the disease: it is the probability of the test returning a positive result in a person with the disease. A **highly sensitive test** will ensure that most patients with the disease will have a positive test result (leading to few false negative results); therefore, **fewer cases of disease are missed**. Given a test with high sensitivity, a negative result would help to rule out a diagnosis (SnNout). This is important during screening for **life-threatening diseases**, even if obtaining a high sensitivity causes an increased numbers of false positives (ie, reduced specificity).

(Choice A) Setting a high cutoff value typically (but not always) produces higher specificity and lower sensitivity.

(Choices B and E) Specificity represents the ability of a test to correctly identify those without the disease. A very specific test has a low rate of false positives, so most healthy patients will have a negative test result (true negative). Given a test with high specificity, a positive result would help to rule in a diagnosis (SpPin). Confirmatory tests with high specificity are often used on patients who test positive on a screening test to ensure that a patient actually has the disease.

(Choice C) Positive predictive value refers to the probability that a disease is present given a positive test result. Positive predictive value depends on disease prevalence. When screening patients for a rare disorder, positive predictive value will often be low due to a high number of false positives.

Educational objective:
The sensitivity of a test refers to its ability to correctly identify those with the disease. A highly sensitive test should always be considered over a highly specific test when screening for life-threatening diseases, where identification of every person with the disease is important.

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Item 2 of 40
Question Id: 19308

A study assessed the association between a new vaccine and traveler's diarrhea (TD). Researchers selected a random sample of people who intended to travel to regions where they were at increased risk for TD and who had received the new vaccine and another independent random sample of people who intended to travel to the same regions and who had not received the new vaccine. These 2 samples of travelers were assessed for the occurrence of TD during the trip and for 7 days after returning home. Which of the following measures of association are the investigators most likely to report?

○ A. Incidence
○ B. Median survival time
○ C. Odds ratio
○ D. Prevalence
○ E. Relative risk

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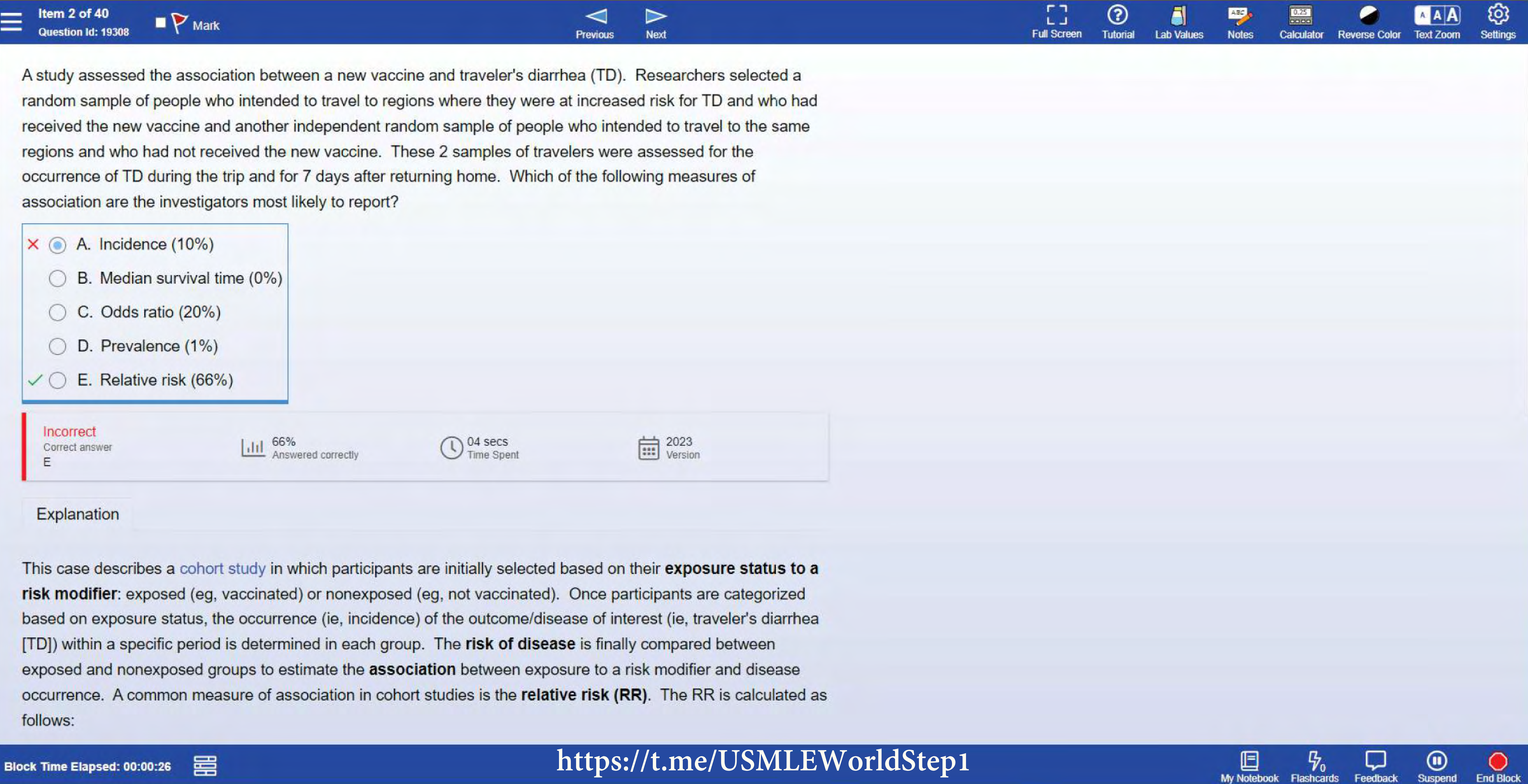
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A study assessed the association between a new vaccine and traveler's diarrhea (TD). Researchers selected a random sample of people who intended to travel to regions where they were at increased risk for TD and who had received the new vaccine and another independent random sample of people who intended to travel to the same regions and who had not received the new vaccine. These 2 samples of travelers were assessed for the occurrence of TD during the trip and for 7 days after returning home. Which of the following measures of association are the investigators most likely to report?

- ✗ ● A. Incidence (10%)
- ○ B. Median survival time (0%)
- ○ C. Odds ratio (20%)
- ○ D. Prevalence (1%)
- ✓ ○ E. Relative risk (66%)

Incorrect
Correct answer
E

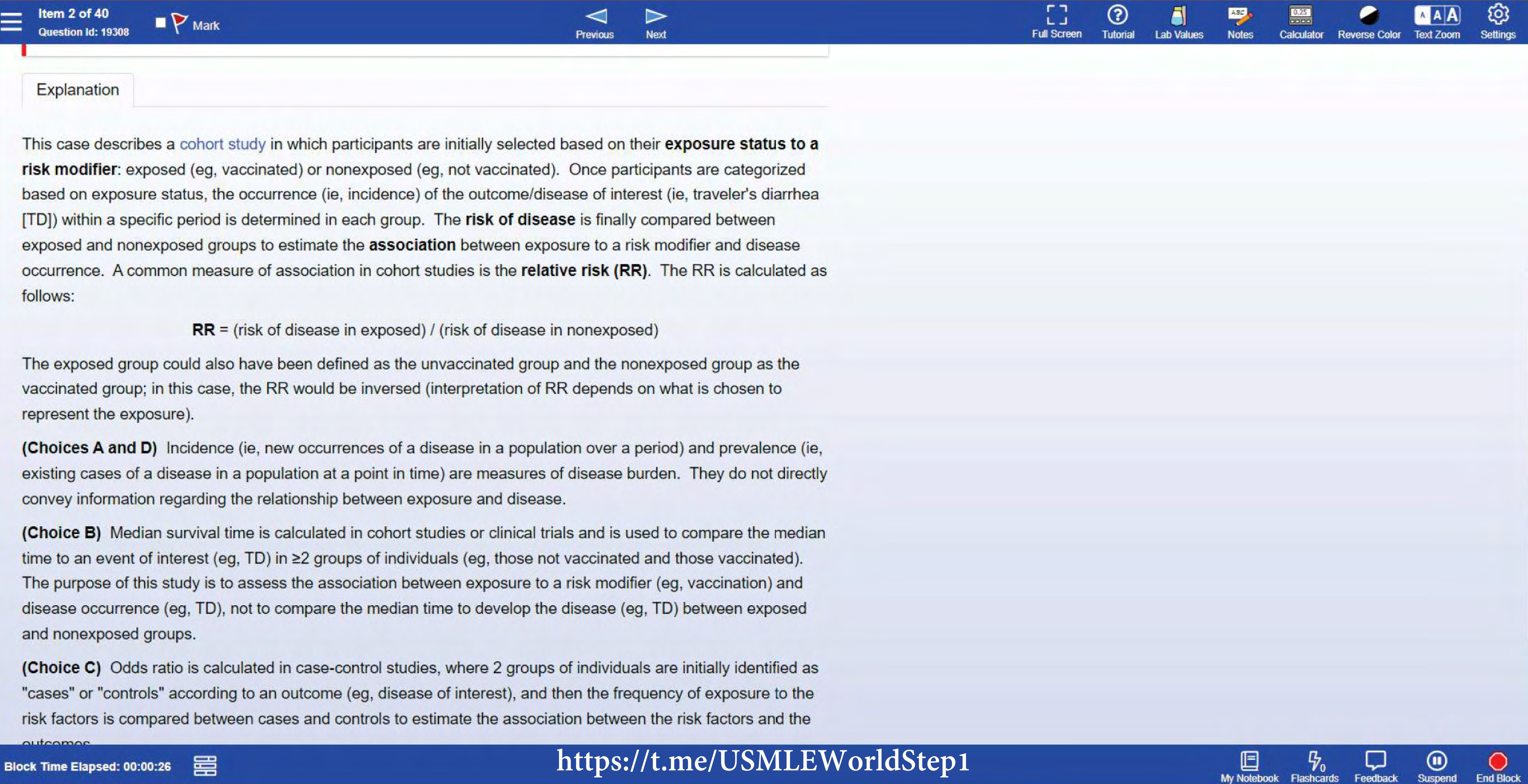
66%
Answered correctly

04 secs
Time Spent

2023
Version

Explanation

This case describes a cohort study in which participants are initially selected based on their **exposure status to a risk modifier**: exposed (eg, vaccinated) or nonexposed (eg, not vaccinated). Once participants are categorized based on exposure status, the occurrence (ie, incidence) of the outcome/disease of interest (ie, traveler's diarrhea [TD]) within a specific period is determined in each group. The **risk of disease** is finally compared between exposed and nonexposed groups to estimate the **association** between exposure to a risk modifier and disease occurrence. A common measure of association in cohort studies is the **relative risk (RR)**. The RR is calculated as follows:



This case describes a cohort study in which participants are initially selected based on their **exposure status to a risk modifier**: exposed (eg, vaccinated) or nonexposed (eg, not vaccinated). Once participants are categorized based on exposure status, the occurrence (ie, incidence) of the outcome/disease of interest (ie, traveler's diarrhea [TD]) within a specific period is determined in each group. The **risk of disease** is finally compared between exposed and nonexposed groups to estimate the **association** between exposure to a risk modifier and disease occurrence. A common measure of association in cohort studies is the **relative risk (RR)**. The RR is calculated as follows:

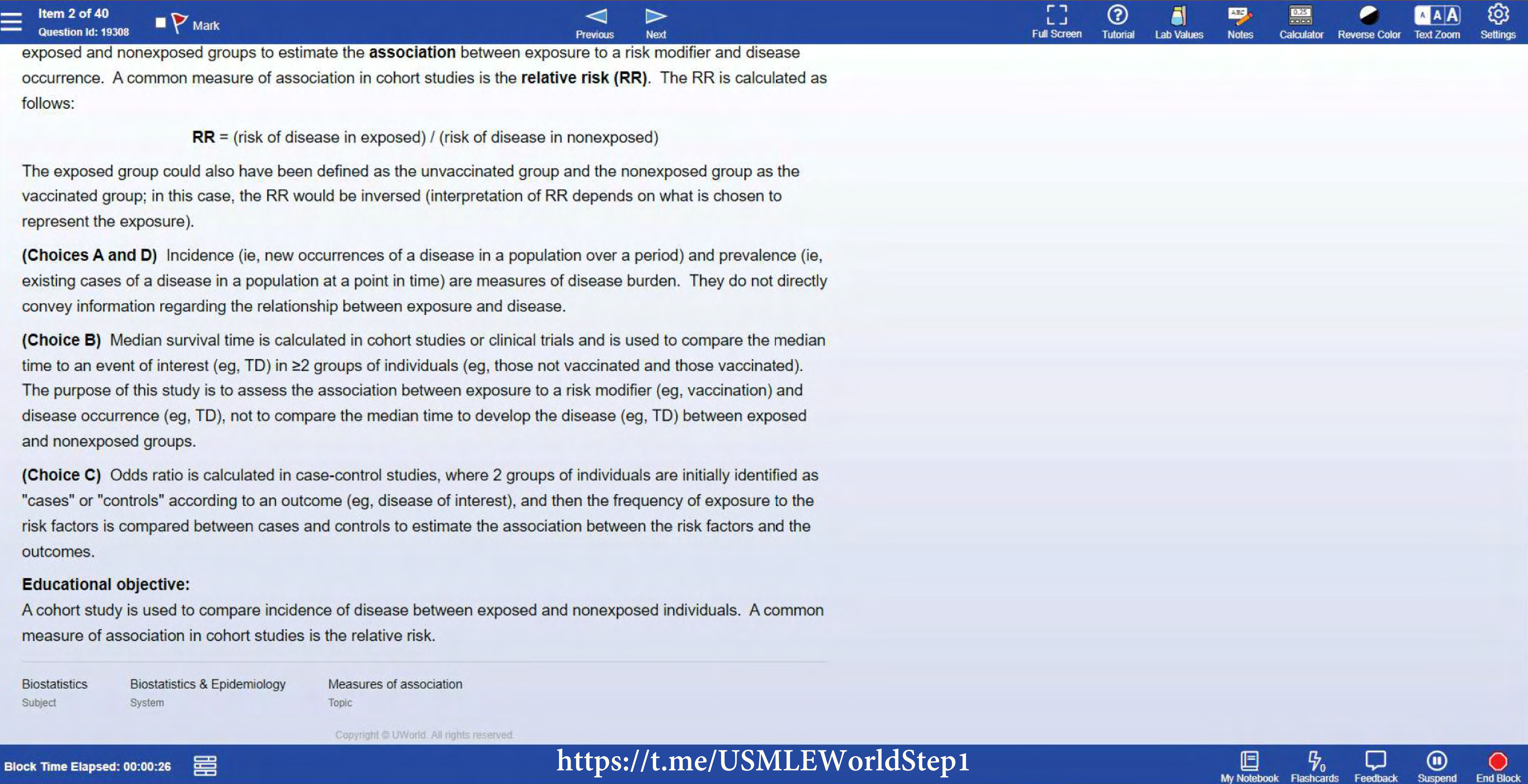
RR = (risk of disease in exposed) / (risk of disease in nonexposed)

The exposed group could also have been defined as the unvaccinated group and the nonexposed group as the vaccinated group; in this case, the RR would be inversed (interpretation of RR depends on what is chosen to represent the exposure).

(Choices A and D) Incidence (ie, new occurrences of a disease in a population over a period) and prevalence (ie, existing cases of a disease in a population at a point in time) are measures of disease burden. They do not directly convey information regarding the relationship between exposure and disease.

(Choice B) Median survival time is calculated in cohort studies or clinical trials and is used to compare the median time to an event of interest (eg, TD) in ≥2 groups of individuals (eg, those not vaccinated and those vaccinated). The purpose of this study is to assess the association between exposure to a risk modifier (eg, vaccination) and disease occurrence (eg, TD), not to compare the median time to develop the disease (eg, TD) between exposed and nonexposed groups.

(Choice C) Odds ratio is calculated in case-control studies, where 2 groups of individuals are initially identified as "cases" or "controls" according to an outcome (eg, disease of interest), and then the frequency of exposure to the risk factors is compared between cases and controls to estimate the association between the risk factors and the outcomes



exposed and nonexposed groups to estimate the **association** between exposure to a risk modifier and disease occurrence. A common measure of association in cohort studies is the **relative risk (RR)**. The RR is calculated as follows:

RR = (risk of disease in exposed) / (risk of disease in nonexposed)

The exposed group could also have been defined as the unvaccinated group and the nonexposed group as the vaccinated group; in this case, the RR would be inversed (interpretation of RR depends on what is chosen to represent the exposure).

(Choices A and D) Incidence (ie, new occurrences of a disease in a population over a period) and prevalence (ie, existing cases of a disease in a population at a point in time) are measures of disease burden. They do not directly convey information regarding the relationship between exposure and disease.

(Choice B) Median survival time is calculated in cohort studies or clinical trials and is used to compare the median time to an event of interest (eg, TD) in ≥2 groups of individuals (eg, those not vaccinated and those vaccinated). The purpose of this study is to assess the association between exposure to a risk modifier (eg, vaccination) and disease occurrence (eg, TD), not to compare the median time to develop the disease (eg, TD) between exposed and nonexposed groups.

(Choice C) Odds ratio is calculated in case-control studies, where 2 groups of individuals are initially identified as "cases" or "controls" according to an outcome (eg, disease of interest), and then the frequency of exposure to the risk factors is compared between cases and controls to estimate the association between the risk factors and the outcomes.

Educational objective:

A cohort study is used to compare incidence of disease between exposed and nonexposed individuals. A common measure of association in cohort studies is the relative risk.

Biostatistics	Biostatistics & Epidemiology	Measures of association
Subject	System	Topic

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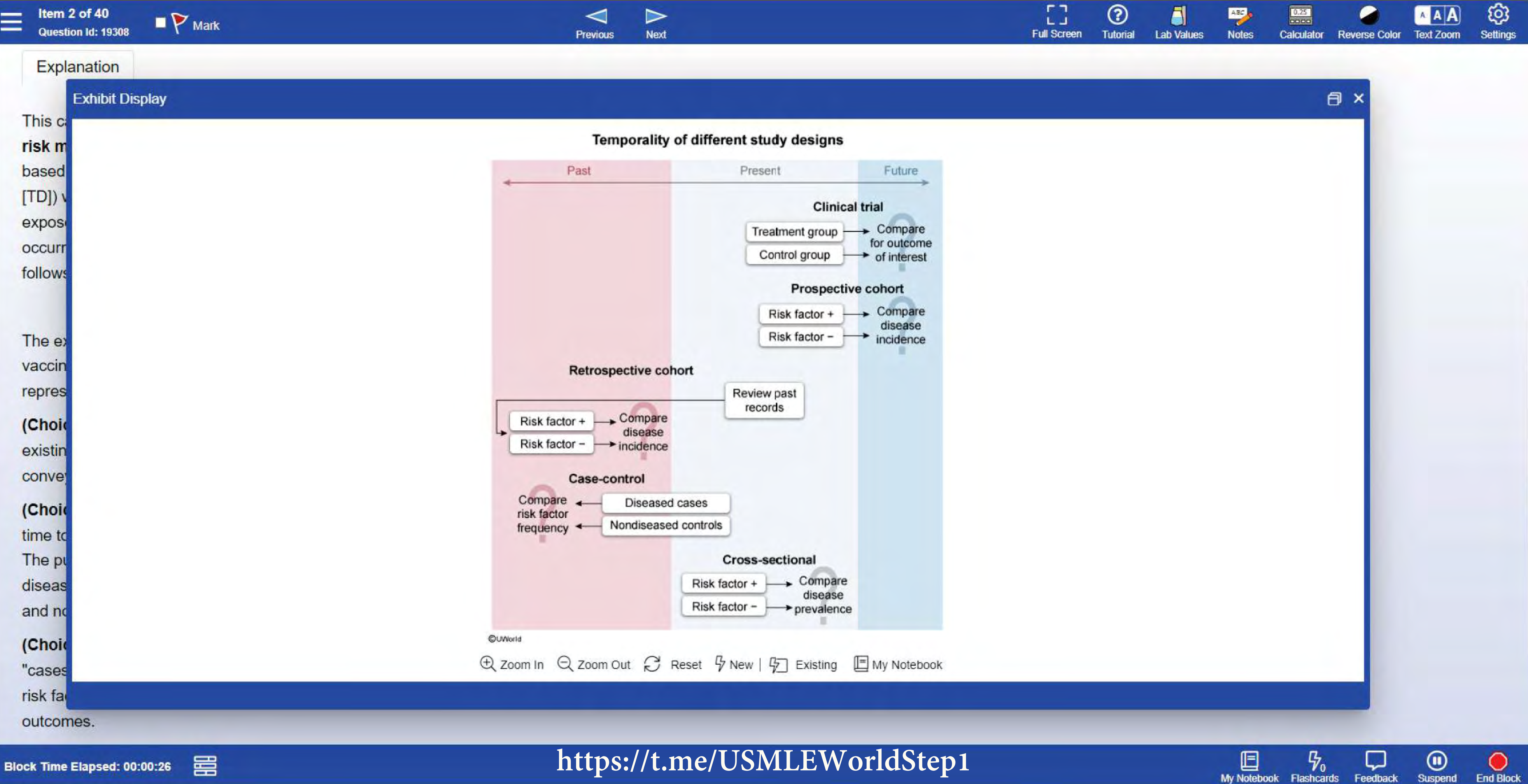
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Control group
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Risk factor –
Compare disease incidence
Retrospective cohort
Review past records
Risk factor +
Risk factor –
Compare disease incidence
Case-control
Diseased cases
Nondiseased controls
Compare risk factor frequency
Cross-sectional
Risk factor +
Risk factor –
Compare disease prevalence
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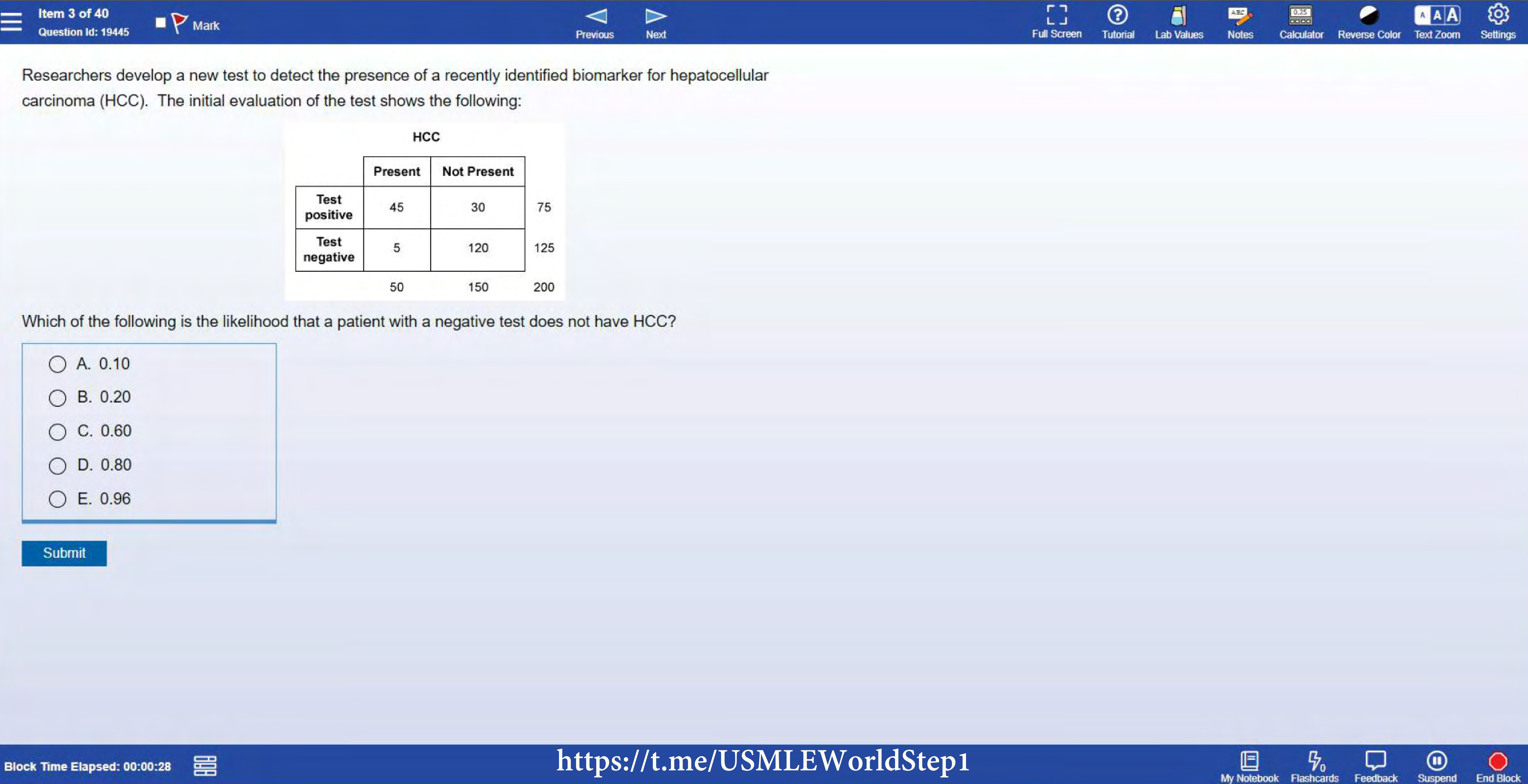
Temporality of different study designs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Researchers develop a new test to detect the presence of a recently identified biomarker for hepatocellular carcinoma (HCC). The initial evaluation of the test shows the following:

HCC

	Present	**Not Present**	
Test positive	45	30	75
Test negative	5	120	125
	50	150	200

Which of the following is the likelihood that a patient with a negative test does not have HCC?

○ A. 0.10

○ B. 0.20

○ C. 0.60

○ D. 0.80

○ E. 0.96

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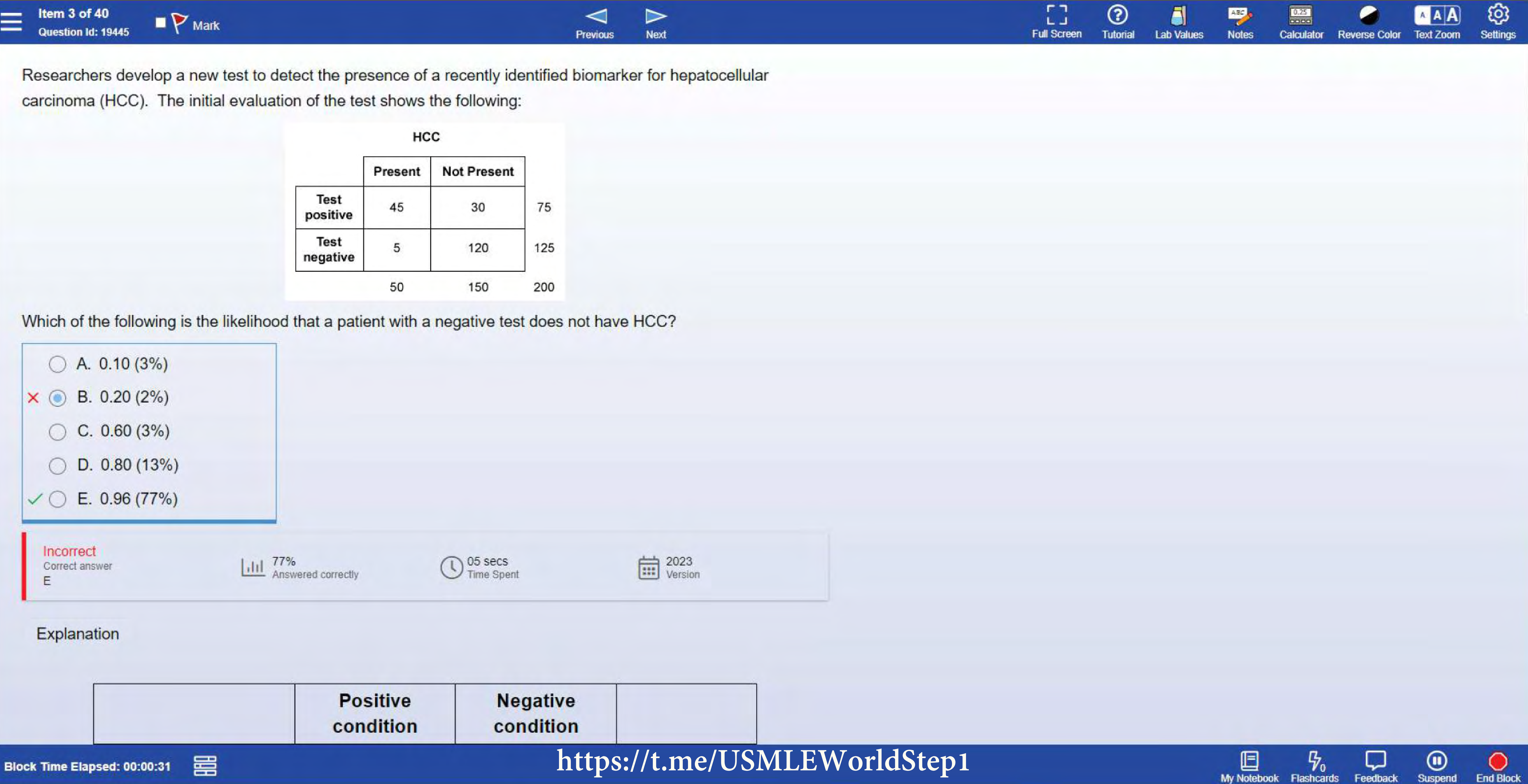
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Researchers develop a new test to detect the presence of a recently identified biomarker for hepatocellular carcinoma (HCC). The initial evaluation of the test shows the following:

HCC

	Present	**Not Present**	
Test positive	45	30	75
Test negative	5	120	125
	50	150	200

Which of the following is the likelihood that a patient with a negative test does not have HCC?

- ○ A. 0.10 (3%)
- ✗ ● B. 0.20 (2%)
- ○ C. 0.60 (3%)
- ○ D. 0.80 (13%)
- ✓ ○ E. 0.96 (77%)

Incorrect
Correct answer
E

77%
Answered correctly

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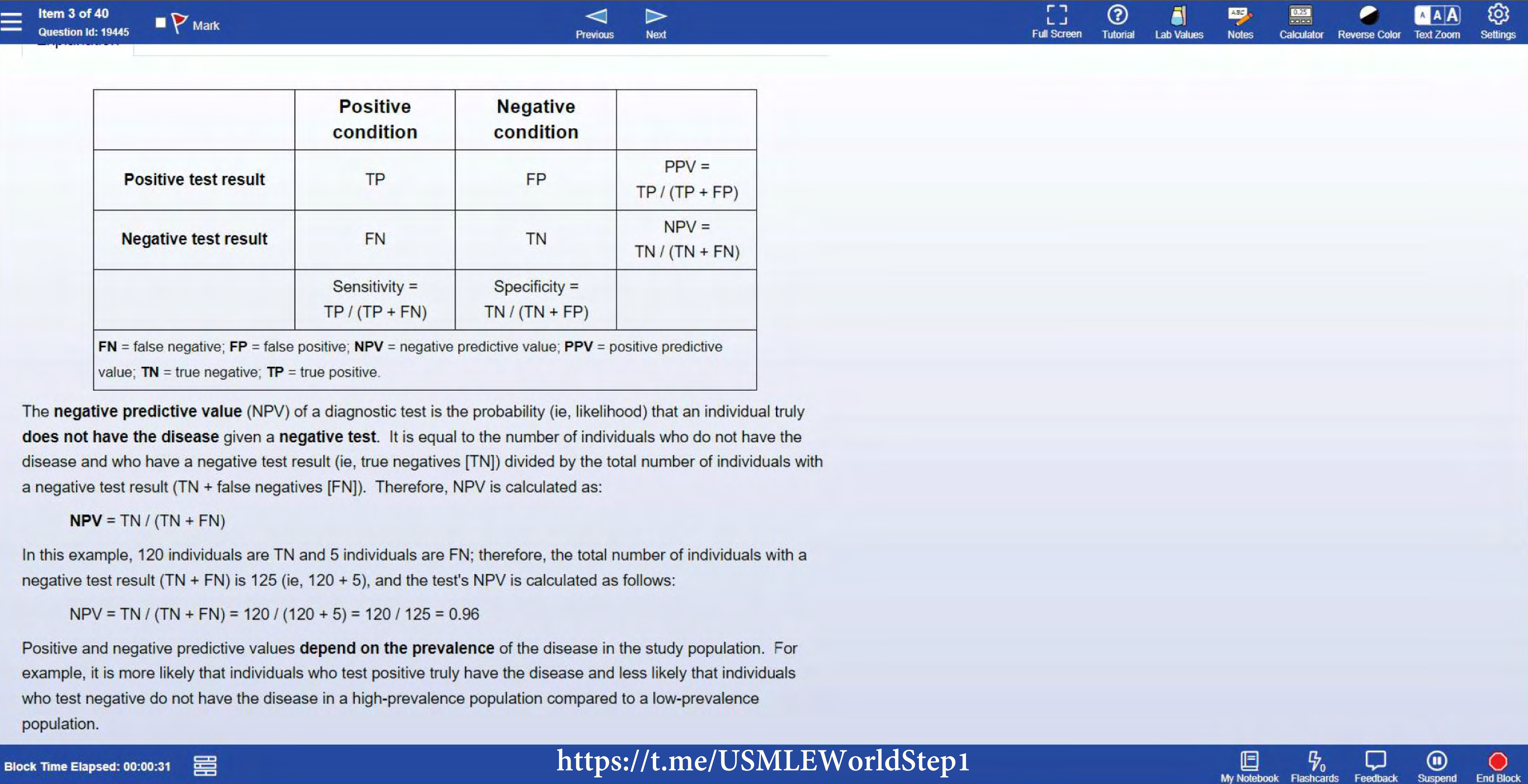
Explanation

	Positive condition	**Negative condition**	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	Positive condition	**Negative condition**	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

The **negative predictive value** (NPV) of a diagnostic test is the probability (ie, likelihood) that an individual truly **does not have the disease** given a **negative test**. It is equal to the number of individuals who do not have the disease and who have a negative test result (ie, true negatives [TN]) divided by the total number of individuals with a negative test result (TN + false negatives [FN]). Therefore, NPV is calculated as:

NPV = TN / (TN + FN)

In this example, 120 individuals are TN and 5 individuals are FN; therefore, the total number of individuals with a negative test result (TN + FN) is 125 (ie, 120 + 5), and the test's NPV is calculated as follows:

NPV = TN / (TN + FN) = 120 / (120 + 5) = 120 / 125 = 0.96

Positive and negative predictive values **depend on the prevalence** of the disease in the study population. For example, it is more likely that individuals who test positive truly have the disease and less likely that individuals who test negative do not have the disease in a high-prevalence population compared to a low-prevalence population.

In this example, 120 individuals are TN and 5 individuals are FN, therefore, the total number of individuals with a negative test result (TN + FN) is 125 (ie, 120 + 5), and the test's NPV is calculated as follows:

NPV = TN / (TN + FN) = 120 / (120 + 5) = 120 / 125 = 0.96

Positive and negative predictive values **depend on the prevalence** of the disease in the study population. For example, it is more likely that individuals who test positive truly have the disease and less likely that individuals who test negative do not have the disease in a high-prevalence population compared to a low-prevalence population.

(Choice A) 0.10 is the false negative rate (FNR). FNR is equal to FN / (FN + TP) and describes the proportion of the individuals who really have the disease for which the test result is negative. It is also known as the miss rate.

(Choice B) 0.20 is the false positive rate (FPR). FPR is equal to FP / (FP + TN) and describes the proportion of the individuals who really do not have the disease for which the test result is positive. It is also known as the fall-out rate.

(Choice C) 0.60 is the overall proportion of TN in the entire study: TN / (TP + TN + FP + FN).

(Choice D) 0.80 is the test's specificity. Specificity is equal to TN / (TN + FP) and describes the proportion of individuals who do not have the disease for which the test result is negative. It is an intrinsic measure of the test's ability to correctly identify individuals without the disease, but by itself, it does not provide enough information to interpret a negative test result in a particular individual.

Educational objective:

Negative predictive value (NPV) is the probability that an individual does not have a disease given a negative test result. It is equal to the number of individuals who do not have the disease and who have a negative test result (ie, true negatives [TN]) divided by the total number of individuals with a negative test result (TN + false negatives [FN]): NPV = TN / (TN + FN).

Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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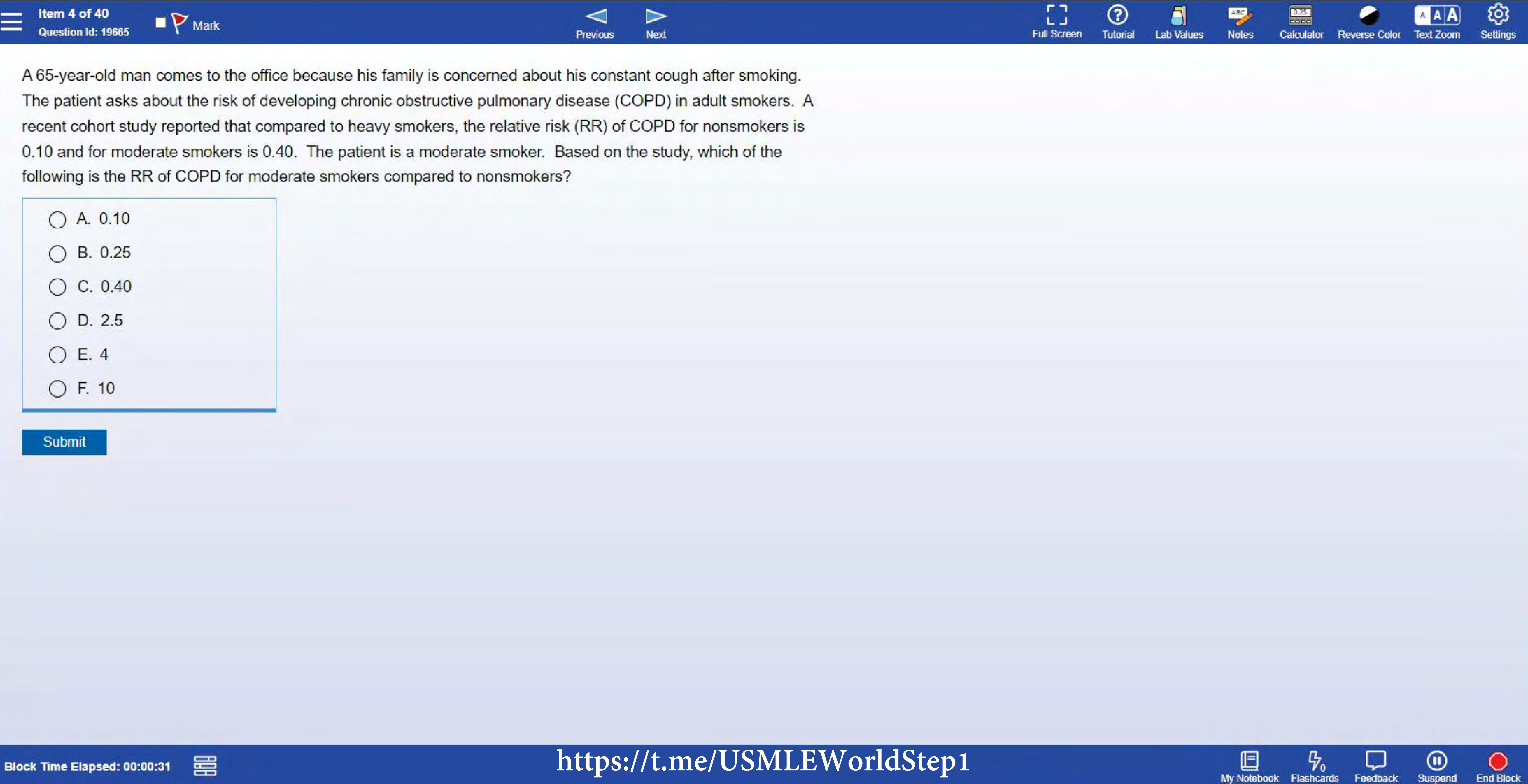
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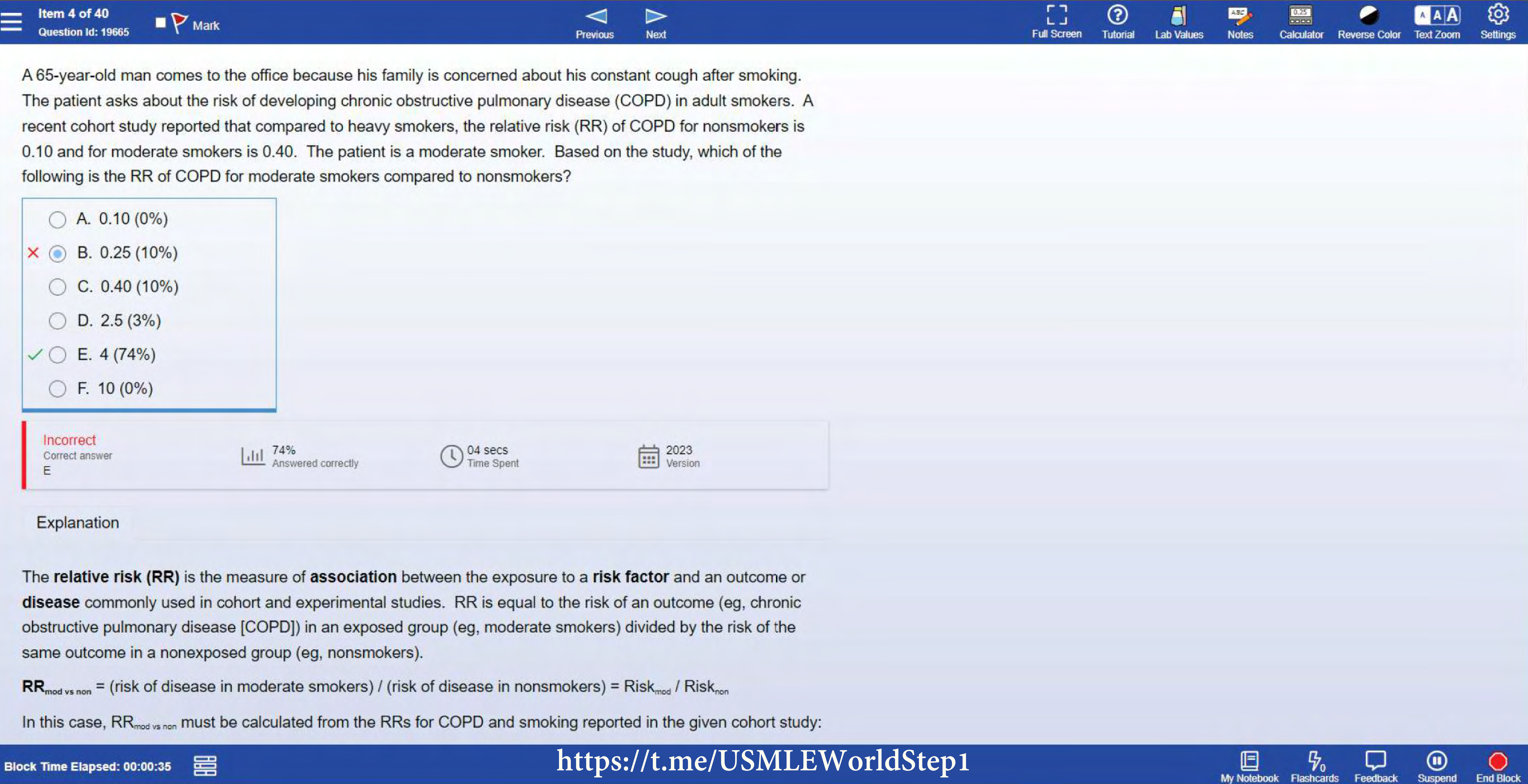
A 65-year-old man comes to the office because his family is concerned about his constant cough after smoking. The patient asks about the risk of developing chronic obstructive pulmonary disease (COPD) in adult smokers. A recent cohort study reported that compared to heavy smokers, the relative risk (RR) of COPD for nonsmokers is 0.10 and for moderate smokers is 0.40. The patient is a moderate smoker. Based on the study, which of the following is the RR of COPD for moderate smokers compared to nonsmokers?

○ A. 0.10
○ B. 0.25
○ C. 0.40
○ D. 2.5
○ E. 4
○ F. 10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- ○ A. 0.10 (0%)
- ✗ ● B. 0.25 (10%)
- ○ C. 0.40 (10%)
- ○ D. 2.5 (3%)
- ✓ ○ E. 4 (74%)
- ○ F. 10 (0%)

Incorrect
Correct answer
E

74%
Answered correctly

04 secs
Time Spent

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Explanation

The **relative risk (RR)** is the measure of **association** between the exposure to a **risk factor** and an outcome or **disease** commonly used in cohort and experimental studies. RR is equal to the risk of an outcome (eg, chronic obstructive pulmonary disease [COPD]) in an exposed group (eg, moderate smokers) divided by the risk of the same outcome in a nonexposed group (eg, nonsmokers).

$\mathbf{RR}_{\text{mod vs non}}$ = (risk of disease in moderate smokers) / (risk of disease in nonsmokers) = $\text{Risk}_{\text{mod}} / \text{Risk}_{\text{non}}$

In this case, $\text{RR}_{\text{mod vs non}}$ must be calculated from the RRs for COPD and smoking reported in the given cohort study:

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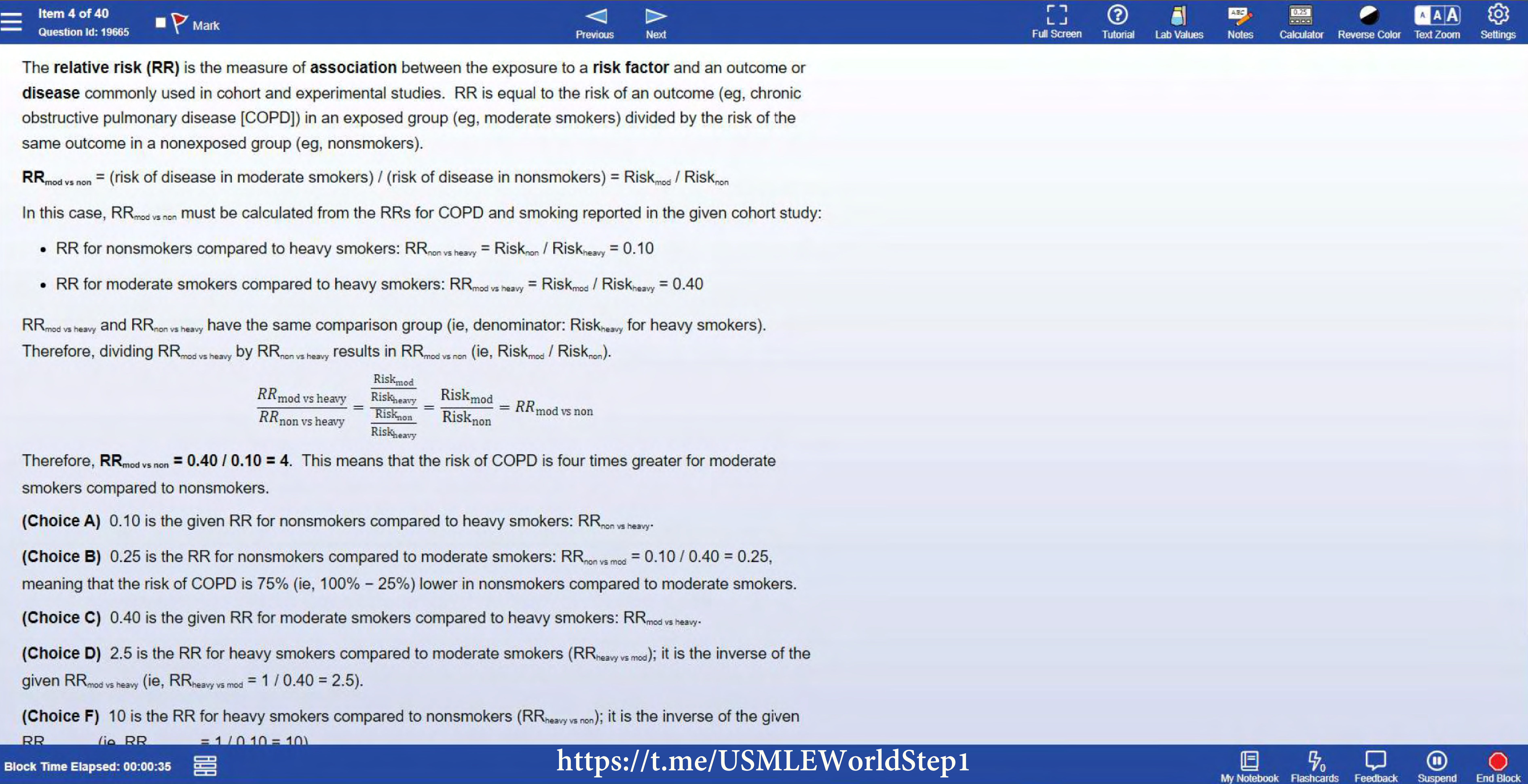


The **relative risk (RR)** is the measure of **association** between the exposure to a **risk factor** and an outcome or **disease** commonly used in cohort and experimental studies. RR is equal to the risk of an outcome (eg, chronic obstructive pulmonary disease [COPD]) in an exposed group (eg, moderate smokers) divided by the risk of the same outcome in a nonexposed group (eg, nonsmokers).

$\text{RR}_{\text{mod vs non}}$ = (risk of disease in moderate smokers) / (risk of disease in nonsmokers) = Risk_{mod} / Risk_{non}

In this case, $\text{RR}_{\text{mod vs non}}$ must be calculated from the RRs for COPD and smoking reported in the given cohort study:

- RR for nonsmokers compared to heavy smokers: $\text{RR}_{\text{non vs heavy}} = \text{Risk}_{\text{non}} / \text{Risk}_{\text{heavy}} = 0.10$
- RR for moderate smokers compared to heavy smokers: $\text{RR}_{\text{mod vs heavy}} = \text{Risk}_{\text{mod}} / \text{Risk}_{\text{heavy}} = 0.40$

$\text{RR}_{\text{mod vs heavy}}$ and $\text{RR}_{\text{non vs heavy}}$ have the same comparison group (ie, denominator: $\text{Risk}_{\text{heavy}}$ for heavy smokers). Therefore, dividing $\text{RR}_{\text{mod vs heavy}}$ by $\text{RR}_{\text{non vs heavy}}$ results in $\text{RR}_{\text{mod vs non}}$ (ie, Risk_{mod} / Risk_{non}).

$$\frac{RR_{\text{mod vs heavy}}}{RR_{\text{non vs heavy}}} = \frac{\frac{\text{Risk}_{\text{mod}}}{\text{Risk}_{\text{heavy}}}}{\frac{\text{Risk}_{\text{non}}}{\text{Risk}_{\text{heavy}}}} = \frac{\text{Risk}_{\text{mod}}}{\text{Risk}_{\text{non}}} = RR_{\text{mod vs non}}$$

Therefore, **$\text{RR}_{\text{mod vs non}} = 0.40 / 0.10 = 4$**. This means that the risk of COPD is four times greater for moderate smokers compared to nonsmokers.

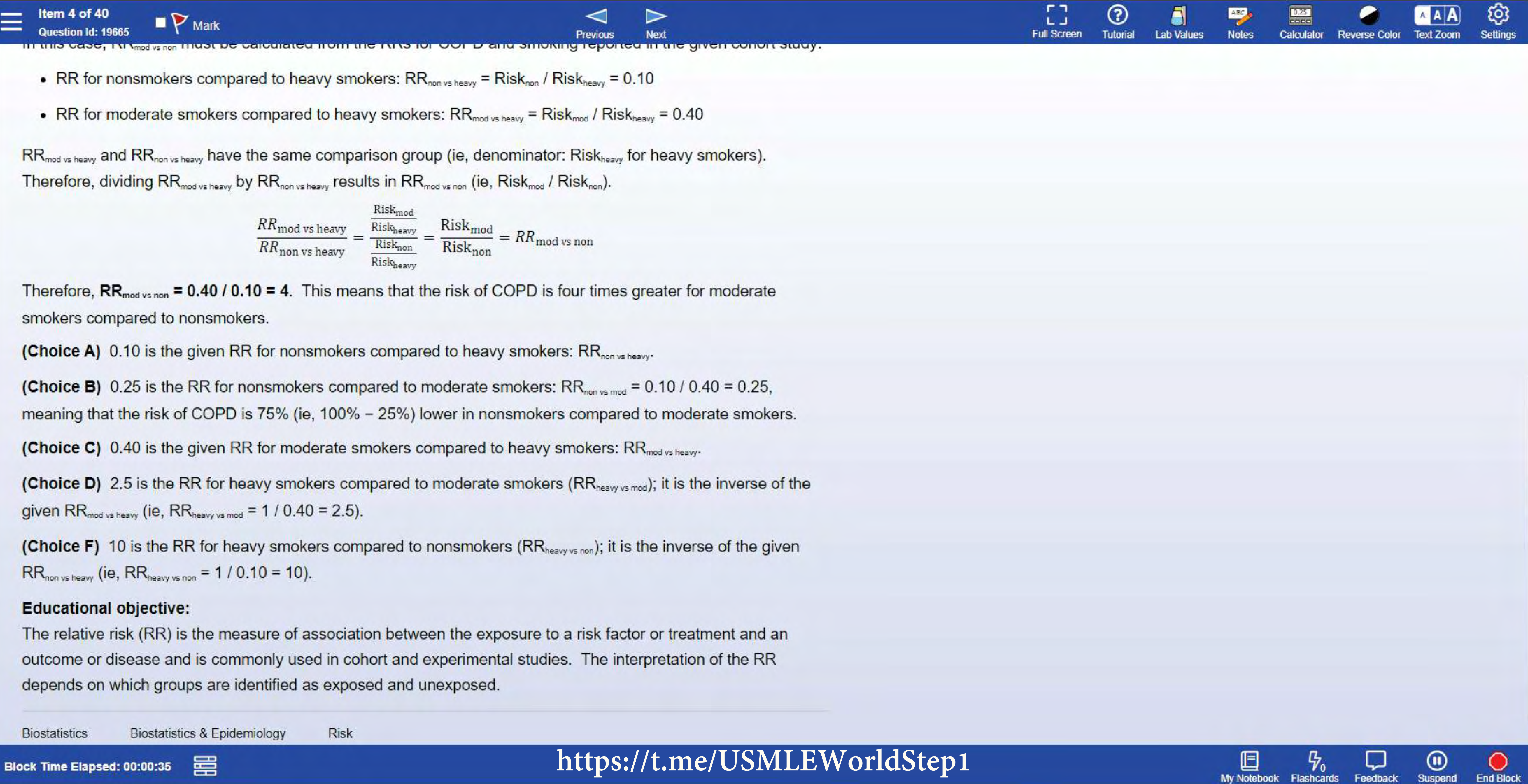
(Choice A) 0.10 is the given RR for nonsmokers compared to heavy smokers: $\text{RR}_{\text{non vs heavy}}$.

(Choice B) 0.25 is the RR for nonsmokers compared to moderate smokers: $\text{RR}_{\text{non vs mod}} = 0.10 / 0.40 = 0.25$, meaning that the risk of COPD is 75% (ie, 100% − 25%) lower in nonsmokers compared to moderate smokers.

(Choice C) 0.40 is the given RR for moderate smokers compared to heavy smokers: $\text{RR}_{\text{mod vs heavy}}$.

(Choice D) 2.5 is the RR for heavy smokers compared to moderate smokers ($\text{RR}_{\text{heavy vs mod}}$); it is the inverse of the given $\text{RR}_{\text{mod vs heavy}}$ (ie, $\text{RR}_{\text{heavy vs mod}} = 1 / 0.40 = 2.5$).

(Choice F) 10 is the RR for heavy smokers compared to nonsmokers ($\text{RR}_{\text{heavy vs non}}$); it is the inverse of the given RR (ie, RR = 1 / 0.10 = 10).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In this case, $RR_{mod\ vs\ non}$ must be calculated from the RRs for COPD and smoking reported in the given cohort study.

- RR for nonsmokers compared to heavy smokers: $RR_{non\ vs\ heavy} = Risk_{non} / Risk_{heavy} = 0.10$
- RR for moderate smokers compared to heavy smokers: $RR_{mod\ vs\ heavy} = Risk_{mod} / Risk_{heavy} = 0.40$

$RR_{mod\ vs\ heavy}$ and $RR_{non\ vs\ heavy}$ have the same comparison group (ie, denominator: $Risk_{heavy}$ for heavy smokers). Therefore, dividing $RR_{mod\ vs\ heavy}$ by $RR_{non\ vs\ heavy}$ results in $RR_{mod\ vs\ non}$ (ie, $Risk_{mod} / Risk_{non}$).

$$\frac{RR_{\text{mod vs heavy}}}{RR_{\text{non vs heavy}}} = \frac{\frac{\text{Risk}_{\text{mod}}}{\text{Risk}_{\text{heavy}}}}{\frac{\text{Risk}_{\text{non}}}{\text{Risk}_{\text{heavy}}}} = \frac{\text{Risk}_{\text{mod}}}{\text{Risk}_{\text{non}}} = RR_{\text{mod vs non}}$$

Therefore, **$RR_{mod\ vs\ non} = 0.40 / 0.10 = 4$**. This means that the risk of COPD is four times greater for moderate smokers compared to nonsmokers.

(Choice A) 0.10 is the given RR for nonsmokers compared to heavy smokers: $RR_{non\ vs\ heavy}$.

(Choice B) 0.25 is the RR for nonsmokers compared to moderate smokers: $RR_{non\ vs\ mod} = 0.10 / 0.40 = 0.25$, meaning that the risk of COPD is 75% (ie, 100% − 25%) lower in nonsmokers compared to moderate smokers.

(Choice C) 0.40 is the given RR for moderate smokers compared to heavy smokers: $RR_{mod\ vs\ heavy}$.

(Choice D) 2.5 is the RR for heavy smokers compared to moderate smokers ($RR_{heavy\ vs\ mod}$); it is the inverse of the given $RR_{mod\ vs\ heavy}$ (ie, $RR_{heavy\ vs\ mod} = 1 / 0.40 = 2.5$).

(Choice F) 10 is the RR for heavy smokers compared to nonsmokers ($RR_{heavy\ vs\ non}$); it is the inverse of the given $RR_{non\ vs\ heavy}$ (ie, $RR_{heavy\ vs\ non} = 1 / 0.10 = 10$).

Educational objective:

The relative risk (RR) is the measure of association between the exposure to a risk factor or treatment and an outcome or disease and is commonly used in cohort and experimental studies. The interpretation of the RR depends on which groups are identified as exposed and unexposed.

Biostatistics | Biostatistics & Epidemiology | Risk

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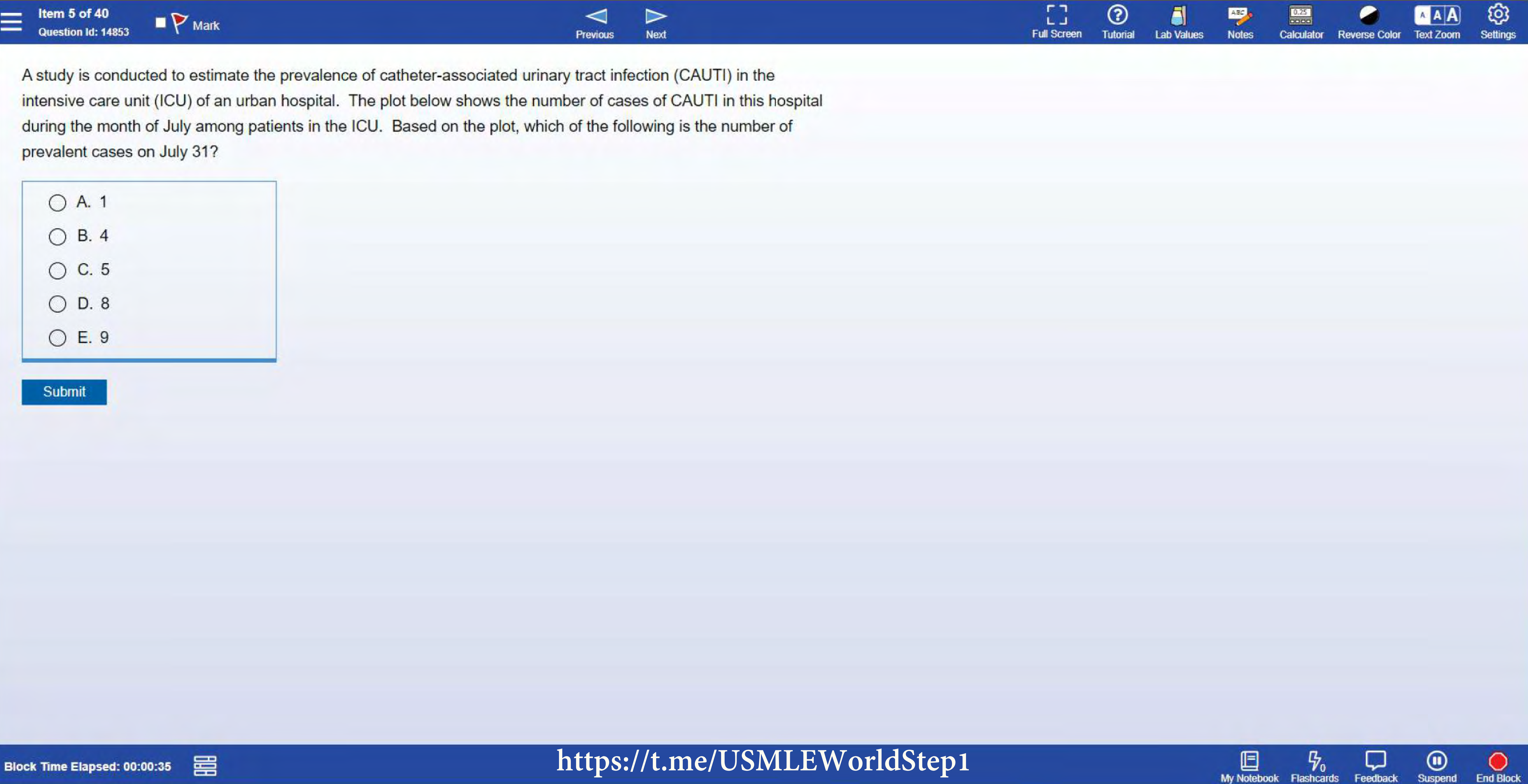
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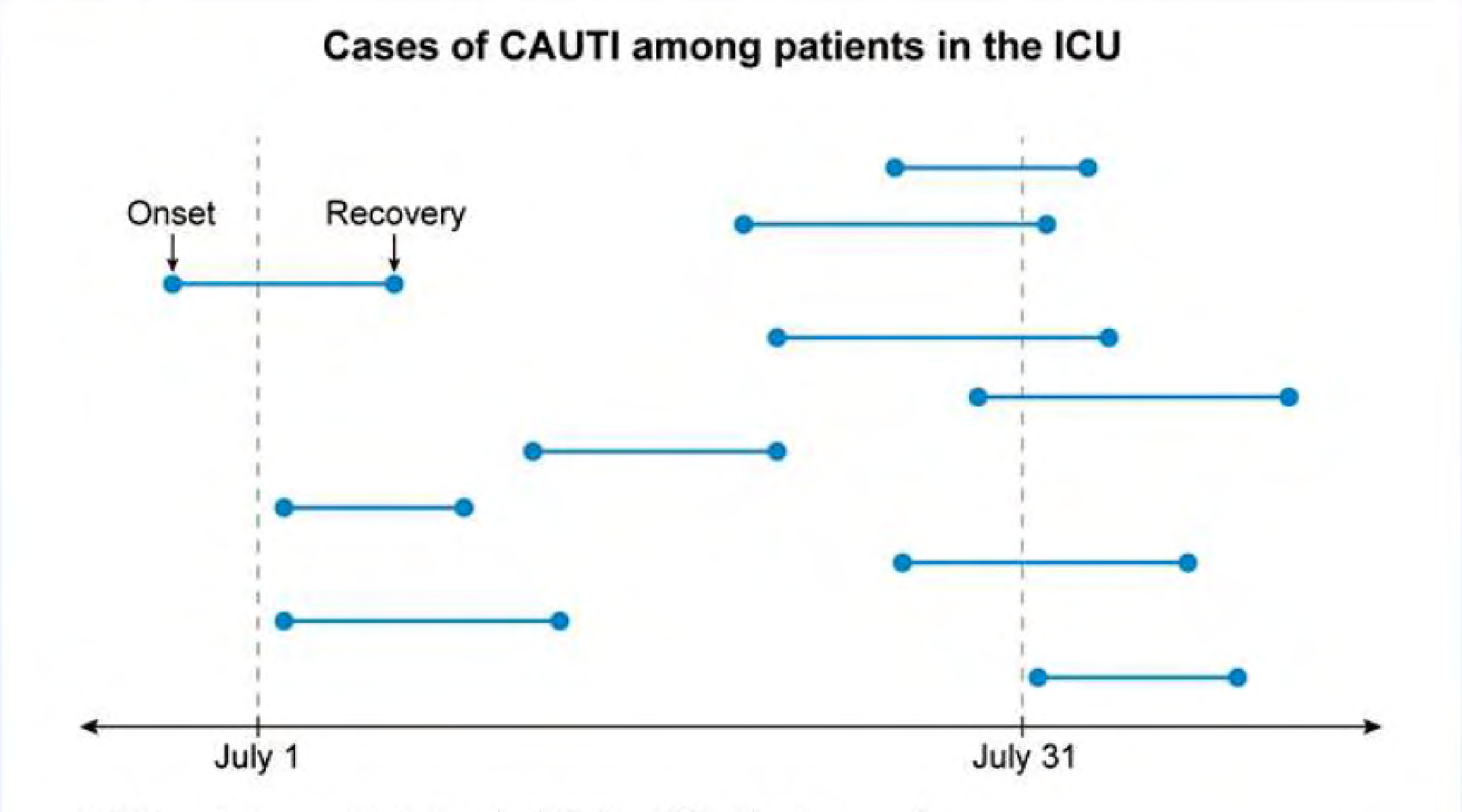
A study is conducted to estimate the prevalence of catheter-associated urinary tract infection (CAUTI) in the intensive care unit (ICU) of an urban hospital. The plot below shows the number of cases of CAUTI in this hospital during the month of July among patients in the ICU. Based on the plot, which of the following is the number of prevalent cases on July 31?

○ A. 1
○ B. 4
○ C. 5
○ D. 8
○ E. 9

A study is conducted to estimate the prevalence of catheter-associated urinary tract infection (CAUTI) in the intensive care unit (ICU) of an urban hospital. The plot below shows the number of cases of CAUTI in this hospital during the month of July among patients in the ICU. Based on the plot, which of the following is the number of prevalent cases on July 31?



CAUTI = catheter-associated urinary tract infection; **ICU** = intensive care unit.

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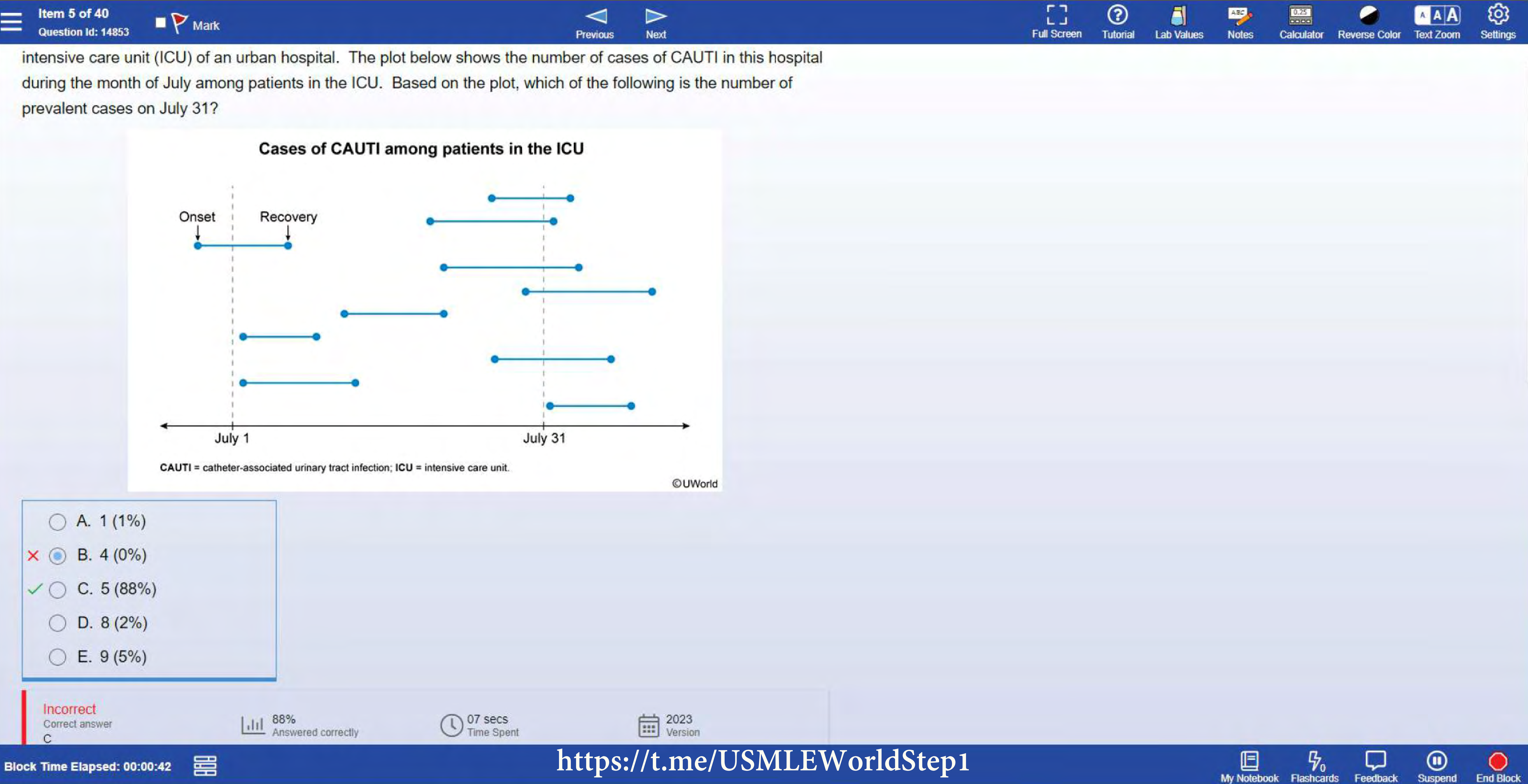
○ A. 1
○ B. 4
○ C. 5
○ D. 8
○ E. 9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intensive care unit (ICU) of an urban hospital. The plot below shows the number of cases of CAUTI in this hospital during the month of July among patients in the ICU. Based on the plot, which of the following is the number of prevalent cases on July 31?

Cases of CAUTI among patients in the ICU

CAUTI = catheter-associated urinary tract infection; **ICU** = intensive care unit.

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- ○ A. 1 (1%)
- ✗ ● B. 4 (0%)
- ✓ ○ C. 5 (88%)
- ○ D. 8 (2%)
- ○ E. 9 (5%)

Incorrect
Correct answer
C

88%
Answered correctly

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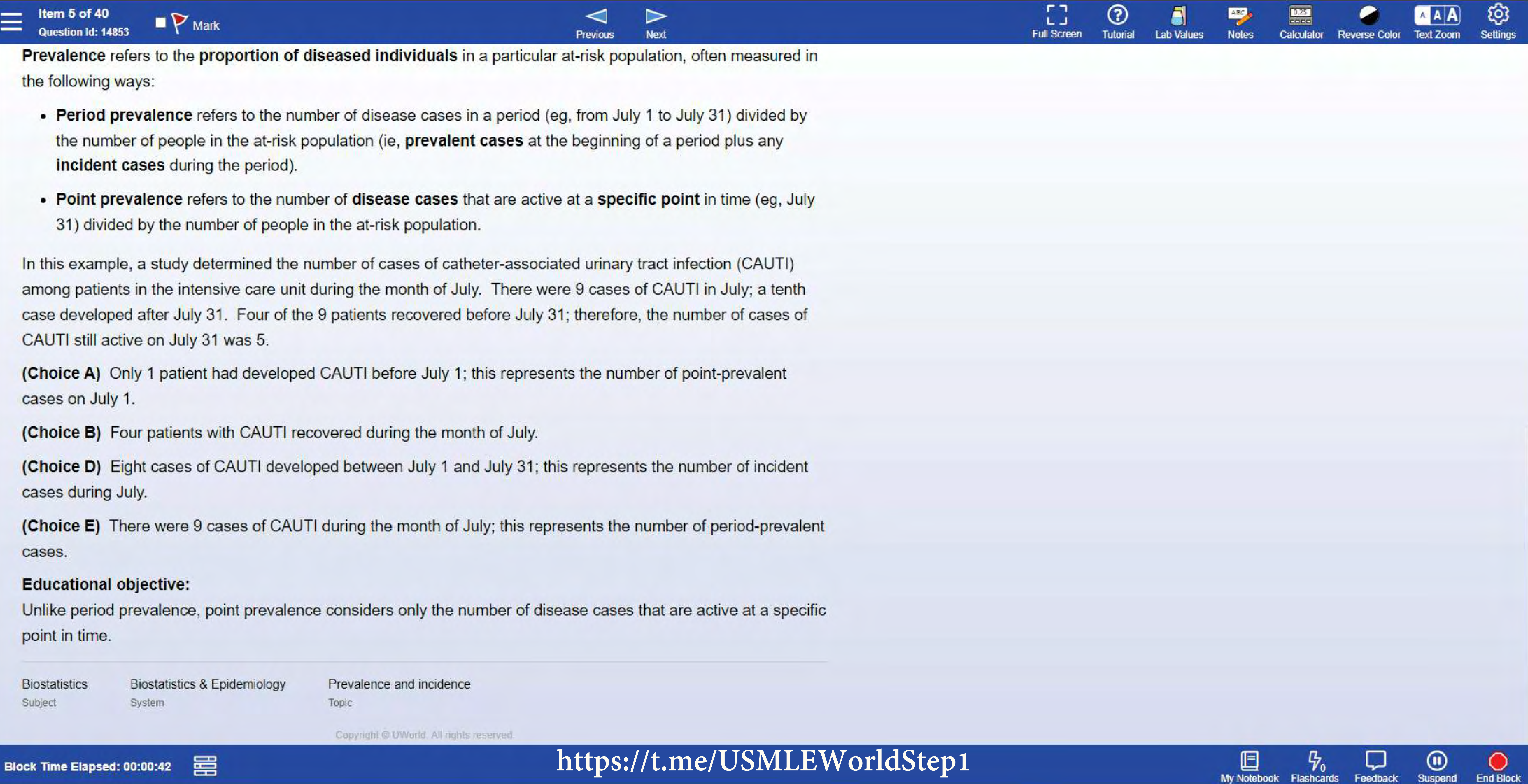
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Prevalence refers to the **proportion of diseased individuals** in a particular at-risk population, often measured in the following ways:

- **Period prevalence** refers to the number of disease cases in a period (eg, from July 1 to July 31) divided by the number of people in the at-risk population (ie, **prevalent cases** at the beginning of a period plus any **incident cases** during the period).
- **Point prevalence** refers to the number of **disease cases** that are active at a **specific point** in time (eg, July 31) divided by the number of people in the at-risk population.

In this example, a study determined the number of cases of catheter-associated urinary tract infection (CAUTI) among patients in the intensive care unit during the month of July. There were 9 cases of CAUTI in July; a tenth case developed after July 31. Four of the 9 patients recovered before July 31; therefore, the number of cases of CAUTI still active on July 31 was 5.

(Choice A) Only 1 patient had developed CAUTI before July 1; this represents the number of point-prevalent cases on July 1.

(Choice B) Four patients with CAUTI recovered during the month of July.

(Choice D) Eight cases of CAUTI developed between July 1 and July 31; this represents the number of incident cases during July.

(Choice E) There were 9 cases of CAUTI during the month of July; this represents the number of period-prevalent cases.

Educational objective:
Unlike period prevalence, point prevalence considers only the number of disease cases that are active at a specific point in time.

Biostatistics	Biostatistics & Epidemiology	Prevalence and incidence
Subject	System	Topic

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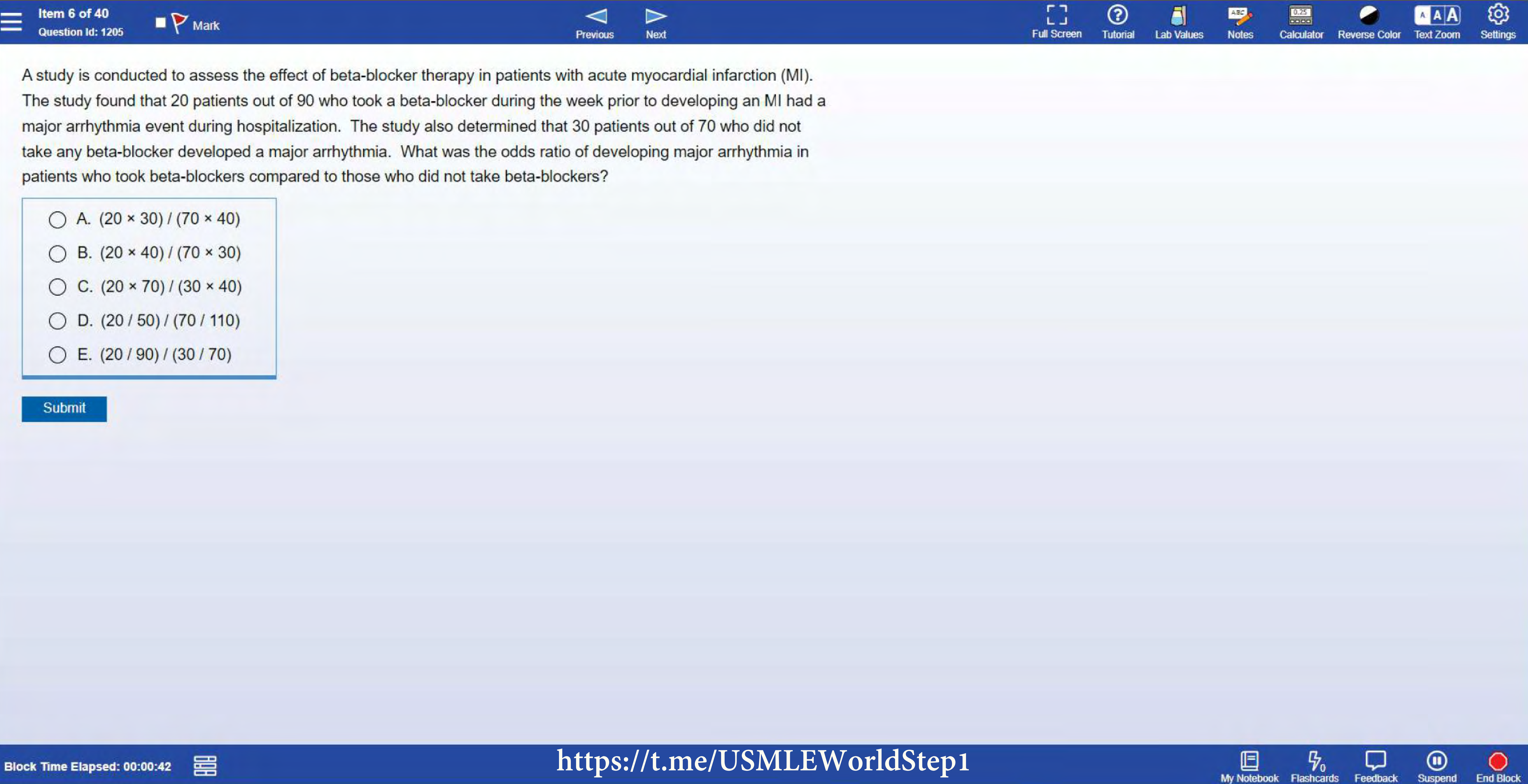
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A study is conducted to assess the effect of beta-blocker therapy in patients with acute myocardial infarction (MI). The study found that 20 patients out of 90 who took a beta-blocker during the week prior to developing an MI had a major arrhythmia event during hospitalization. The study also determined that 30 patients out of 70 who did not take any beta-blocker developed a major arrhythmia. What was the odds ratio of developing major arrhythmia in patients who took beta-blockers compared to those who did not take beta-blockers?

○ A. (20 × 30) / (70 × 40)
○ B. (20 × 40) / (70 × 30)
○ C. (20 × 70) / (30 × 40)
○ D. (20 / 50) / (70 / 110)
○ E. (20 / 90) / (30 / 70)

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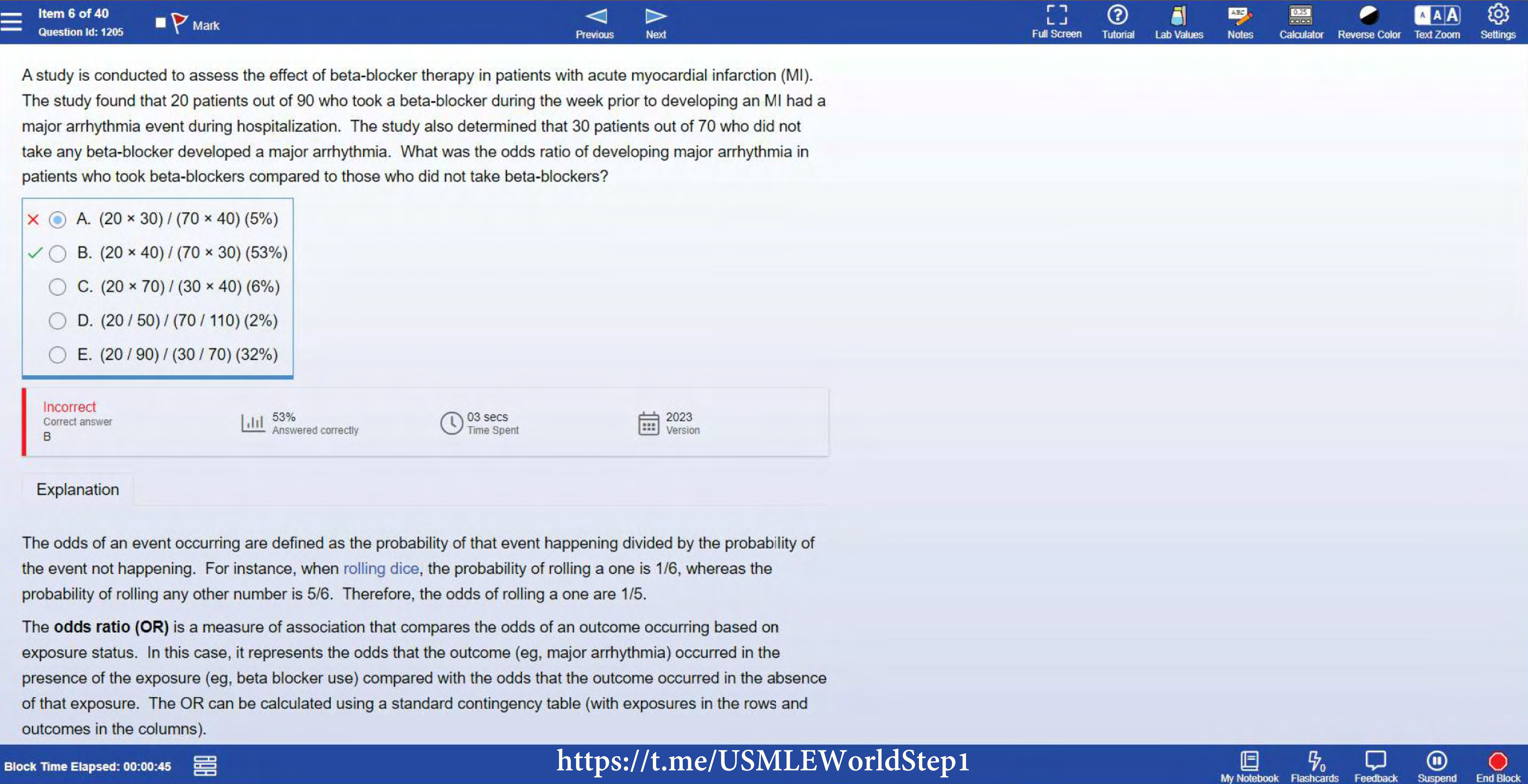
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- ✗ ● A. (20 × 30) / (70 × 40) (5%)
- ✓ ○ B. (20 × 40) / (70 × 30) (53%)
- ○ C. (20 × 70) / (30 × 40) (6%)
- ○ D. (20 / 50) / (70 / 110) (2%)
- ○ E. (20 / 90) / (30 / 70) (32%)

Incorrect
Correct answer
B

53%
Answered correctly

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Explanation

The odds of an event occurring are defined as the probability of that event happening divided by the probability of the event not happening. For instance, when rolling dice, the probability of rolling a one is 1/6, whereas the probability of rolling any other number is 5/6. Therefore, the odds of rolling a one are 1/5.

The **odds ratio (OR)** is a measure of association that compares the odds of an outcome occurring based on exposure status. In this case, it represents the odds that the outcome (eg, major arrhythmia) occurred in the presence of the exposure (eg, beta blocker use) compared with the odds that the outcome occurred in the absence of that exposure. The OR can be calculated using a standard contingency table (with exposures in the rows and outcomes in the columns).

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Explanation

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	Major arrhythmia	**No arrhythmia**	
Beta blocker (exposed group)	20 (a)	70 (b)	90
No beta blocker (unexposed group)	30 (c)	40 (d)	70
	50	110	

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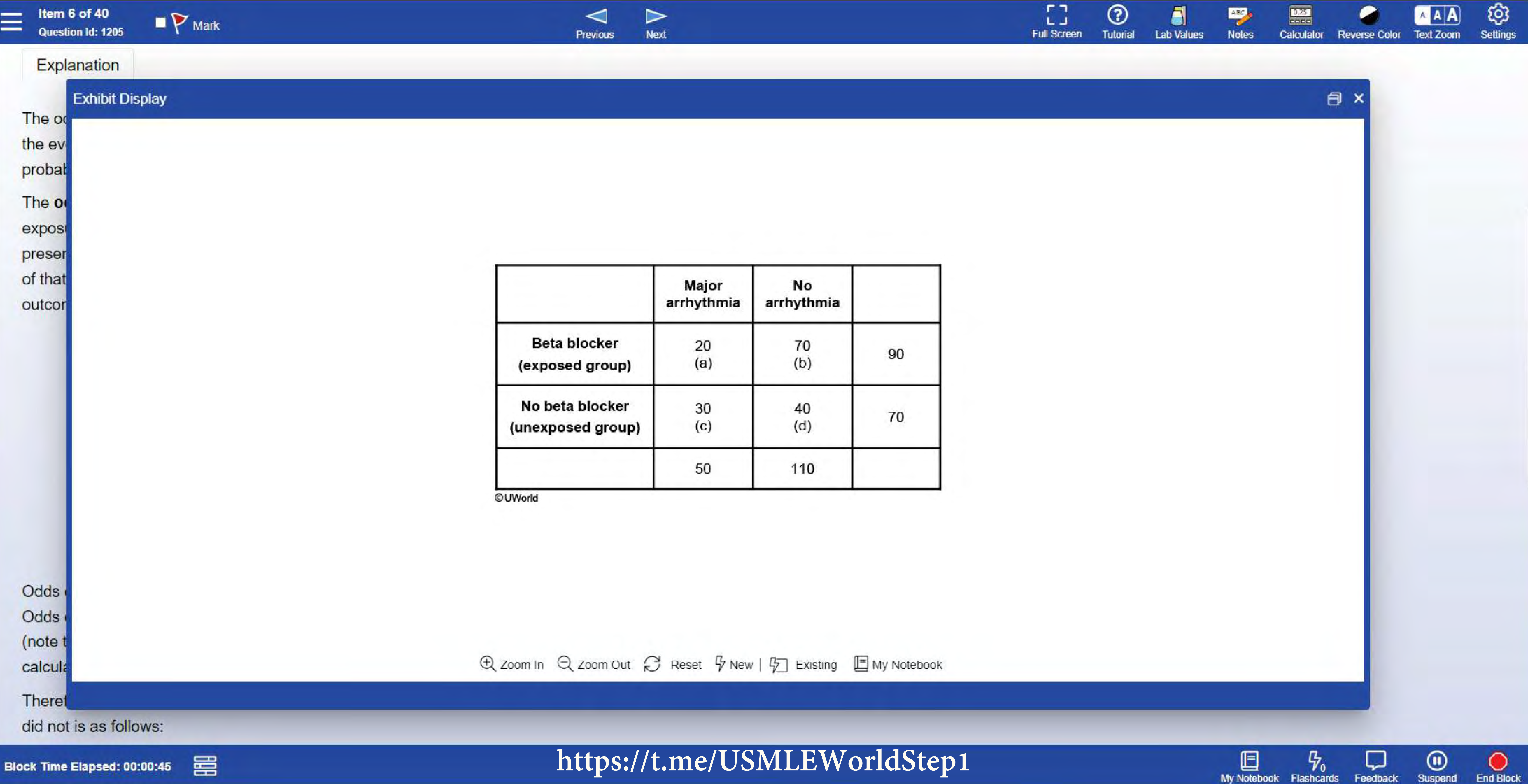
Odds of developing major arrhythmia in exposed group = 20/70
Odds of developing major arrhythmia in unexposed group = 30/40
(note that the total number of people in the exposed and unexposed groups is **not** used to calculate odds, unlike calculating probabilities)

Therefore, the OR of developing a major arrhythmia in patients who took beta blockers compared with those who did not is as follows: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	Major arrhythmia	No arrhythmia	
Beta blocker (exposed group)	20 (a)	70 (b)	90
No beta blocker (unexposed group)	30 (c)	40 (d)	70
	50	110	

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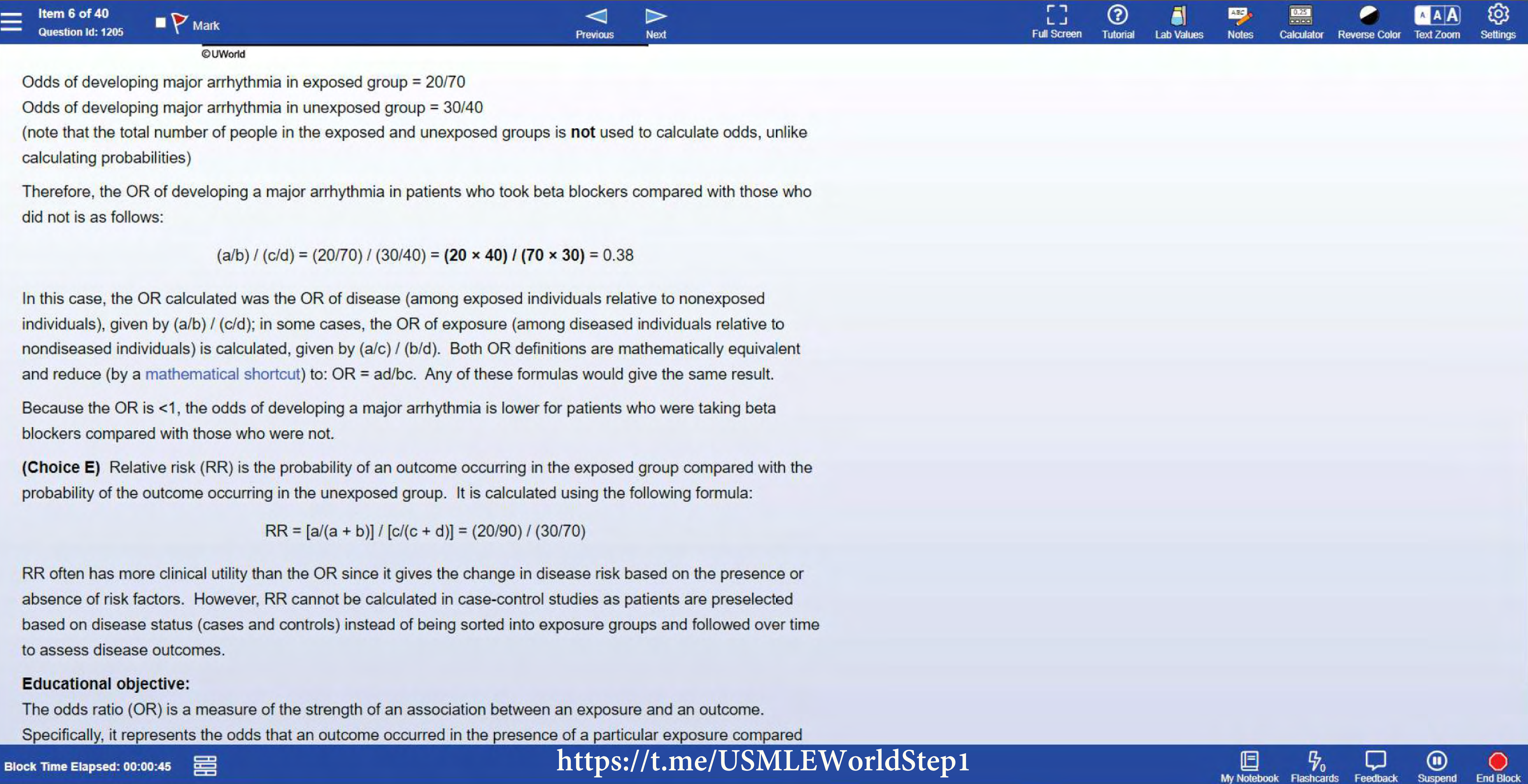
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Odds of developing major arrhythmia in exposed group = 20/70
Odds of developing major arrhythmia in unexposed group = 30/40
(note that the total number of people in the exposed and unexposed groups is **not** used to calculate odds, unlike calculating probabilities)

Therefore, the OR of developing a major arrhythmia in patients who took beta blockers compared with those who did not is as follows:

$$(a/b) / (c/d) = (20/70) / (30/40) = \mathbf{(20 \times 40) / (70 \times 30)} = 0.38$$

In this case, the OR calculated was the OR of disease (among exposed individuals relative to nonexposed individuals), given by (a/b) / (c/d); in some cases, the OR of exposure (among diseased individuals relative to nondiseased individuals) is calculated, given by (a/c) / (b/d). Both OR definitions are mathematically equivalent and reduce (by a mathematical shortcut) to: OR = ad/bc. Any of these formulas would give the same result.

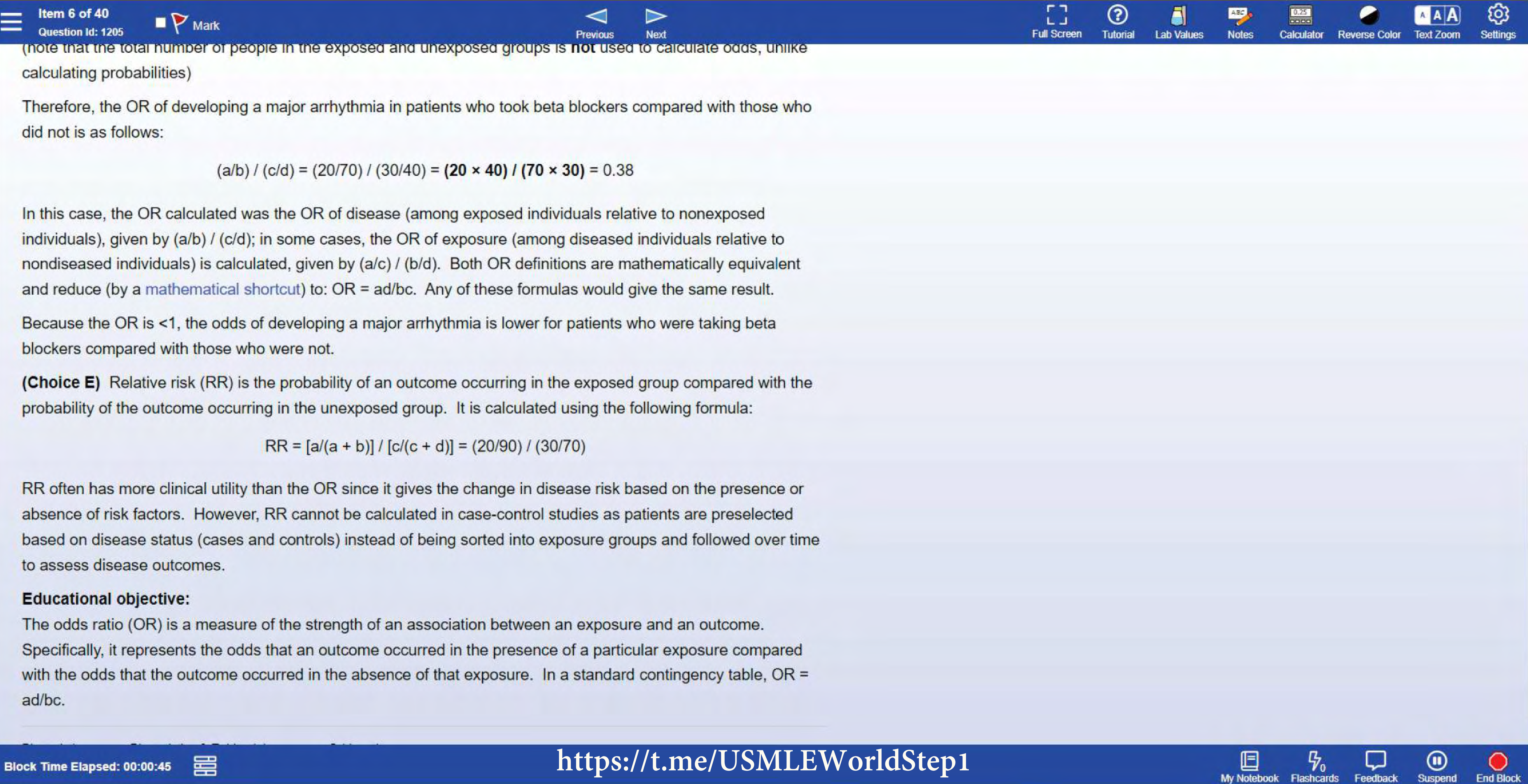
Because the OR is <1, the odds of developing a major arrhythmia is lower for patients who were taking beta blockers compared with those who were not.

(Choice E) Relative risk (RR) is the probability of an outcome occurring in the exposed group compared with the probability of the outcome occurring in the unexposed group. It is calculated using the following formula:

$$RR = [a/(a + b)] / [c/(c + d)] = (20/90) / (30/70)$$

RR often has more clinical utility than the OR since it gives the change in disease risk based on the presence or absence of risk factors. However, RR cannot be calculated in case-control studies as patients are preselected based on disease status (cases and controls) instead of being sorted into exposure groups and followed over time to assess disease outcomes.

Educational objective:
The odds ratio (OR) is a measure of the strength of an association between an exposure and an outcome. Specifically, it represents the odds that an outcome occurred in the presence of a particular exposure compared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$$RR = [a/(a + b)] / [c/(c + d)] = (20/90) / (30/70)$$

RR often has more clinical utility than the OR since it gives the change in disease risk based on the presence or absence of risk factors. However, RR cannot be calculated in case-control studies as patients are preselected based on disease status (cases and controls) instead of being sorted into exposure groups and followed over time to assess disease outcomes.

Educational objective:
The odds ratio (OR) is a measure of the strength of an association between an exposure and an outcome. Specifically, it represents the odds that an outcome occurred in the presence of a particular exposure compared with the odds that the outcome occurred in the absence of that exposure. In a standard contingency table, OR = ad/bc.

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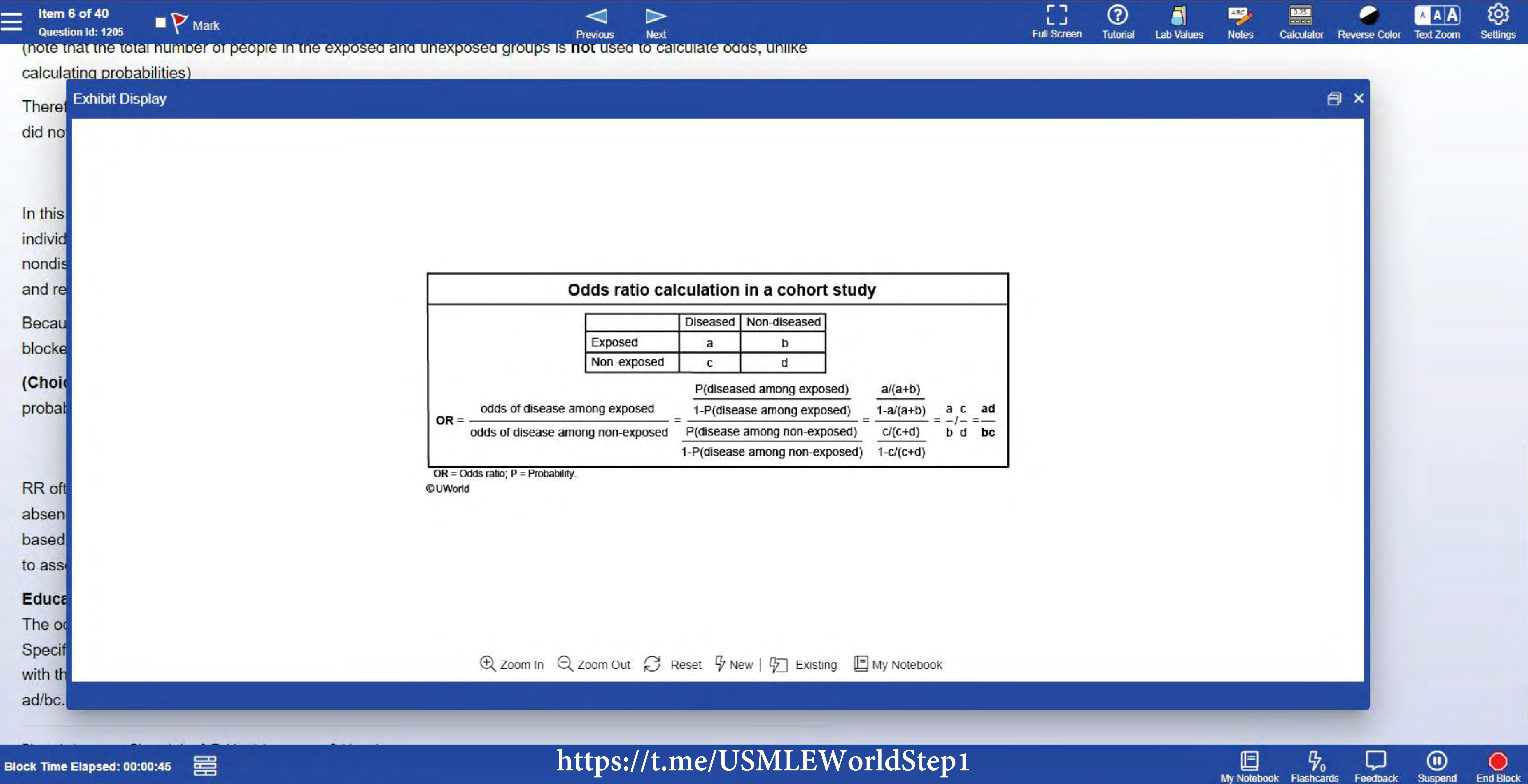
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(note that the total number of people in the exposed and unexposed groups is **not** used to calculate odds, unlike calculating probabilities)

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Odds ratio calculation in a cohort study

	Diseased	Non-diseased
Exposed	a	b
Non-exposed	c	d

$$\textbf{OR} = \frac{\text{odds of disease among exposed}}{\text{odds of disease among non-exposed}} = \frac{\dfrac{\text{P(diseased among exposed)}}{\text{1-P(disease among exposed)}}}{\dfrac{\text{P(disease among non-exposed)}}{\text{1-P(disease among non-exposed)}}} = \frac{\dfrac{a/(a+b)}{1-a/(a+b)}}{\dfrac{c/(c+d)}{1-c/(c+d)}} = \frac{a}{b} / \frac{c}{d} = \frac{\mathbf{ad}}{\mathbf{bc}}$$

OR = Odds ratio; P = Probability.

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○ D. (20 / 50) / (70 / 110) (2%)

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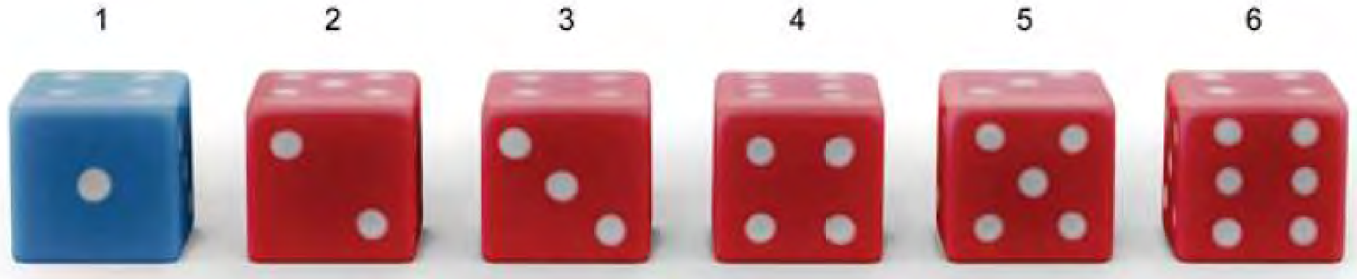
Odds vs probability



Probability of rolling 1: 1/6

Odds of rolling 1: (1/6) / (5/6) = 1/5

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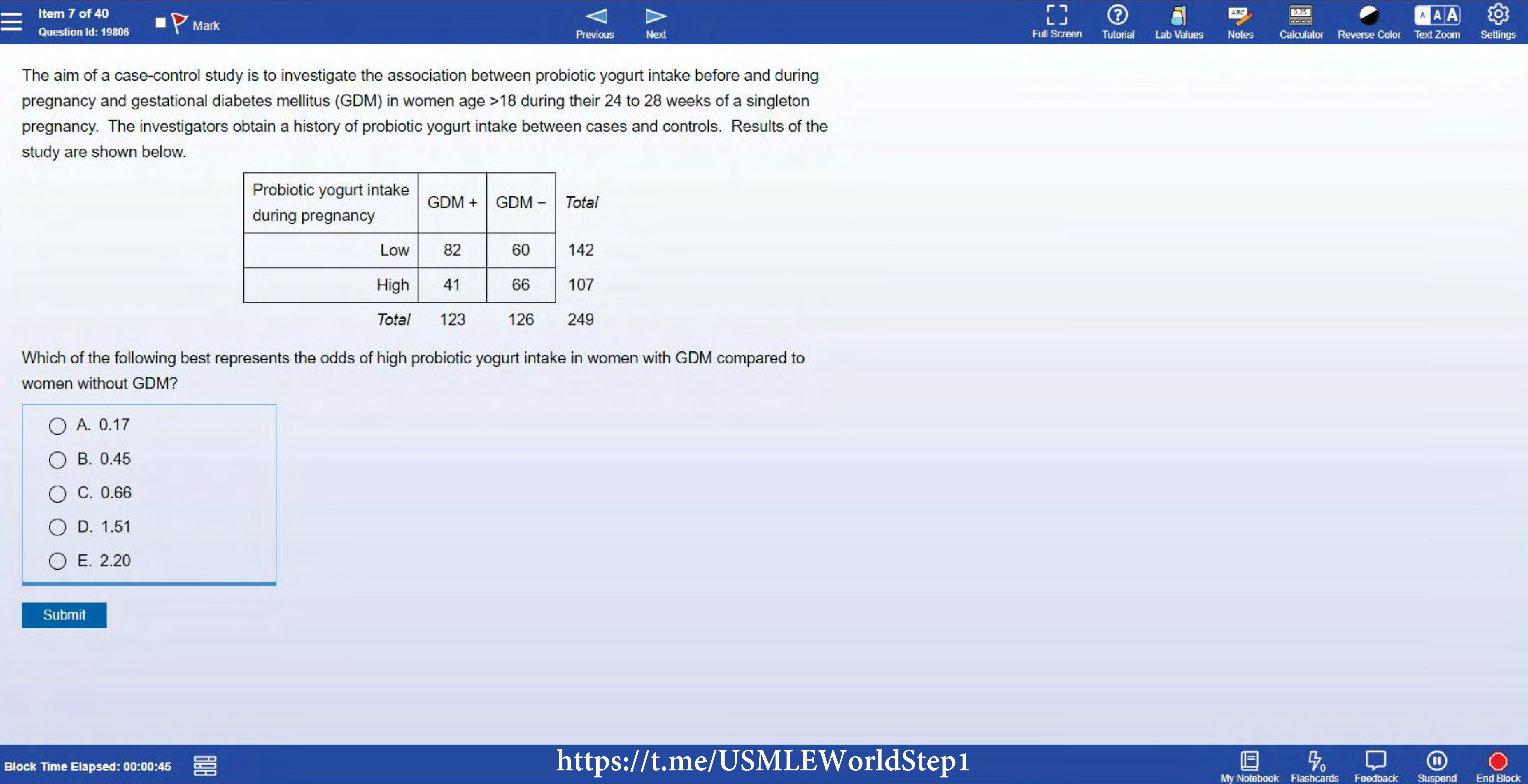
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The aim of a case-control study is to investigate the association between probiotic yogurt intake before and during pregnancy and gestational diabetes mellitus (GDM) in women age >18 during their 24 to 28 weeks of a singleton pregnancy. The investigators obtain a history of probiotic yogurt intake between cases and controls. Results of the study are shown below.

Probiotic yogurt intake during pregnancy	GDM +	GDM −	*Total*
Low	82	60	142
High	41	66	107
Total	123	126	249

Which of the following best represents the odds of high probiotic yogurt intake in women with GDM compared to women without GDM?

○ A. 0.17
○ B. 0.45
○ C. 0.66
○ D. 1.51
○ E. 2.20

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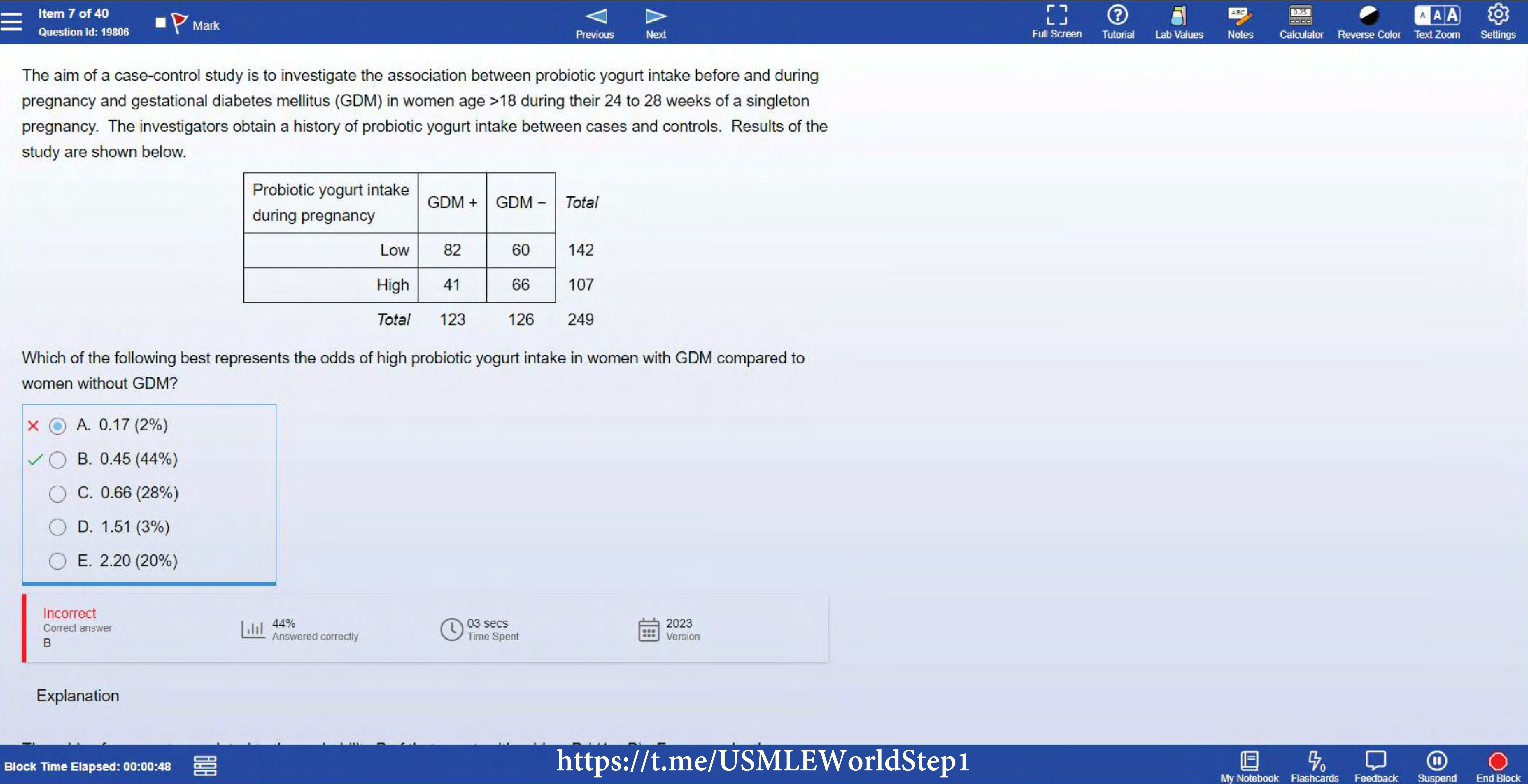
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Probiotic yogurt intake during pregnancy	GDM +	GDM −	*Total*
Low	82	60	142
High	41	66	107
Total	123	126	249

Which of the following best represents the odds of high probiotic yogurt intake in women with GDM compared to women without GDM?

- ✗ ● A. 0.17 (2%)
- ✓ ○ B. 0.45 (44%)
- ○ C. 0.66 (28%)
- ○ D. 1.51 (3%)
- ○ E. 2.20 (20%)

Incorrect
Correct answer
B

44%
Answered correctly

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Explanation

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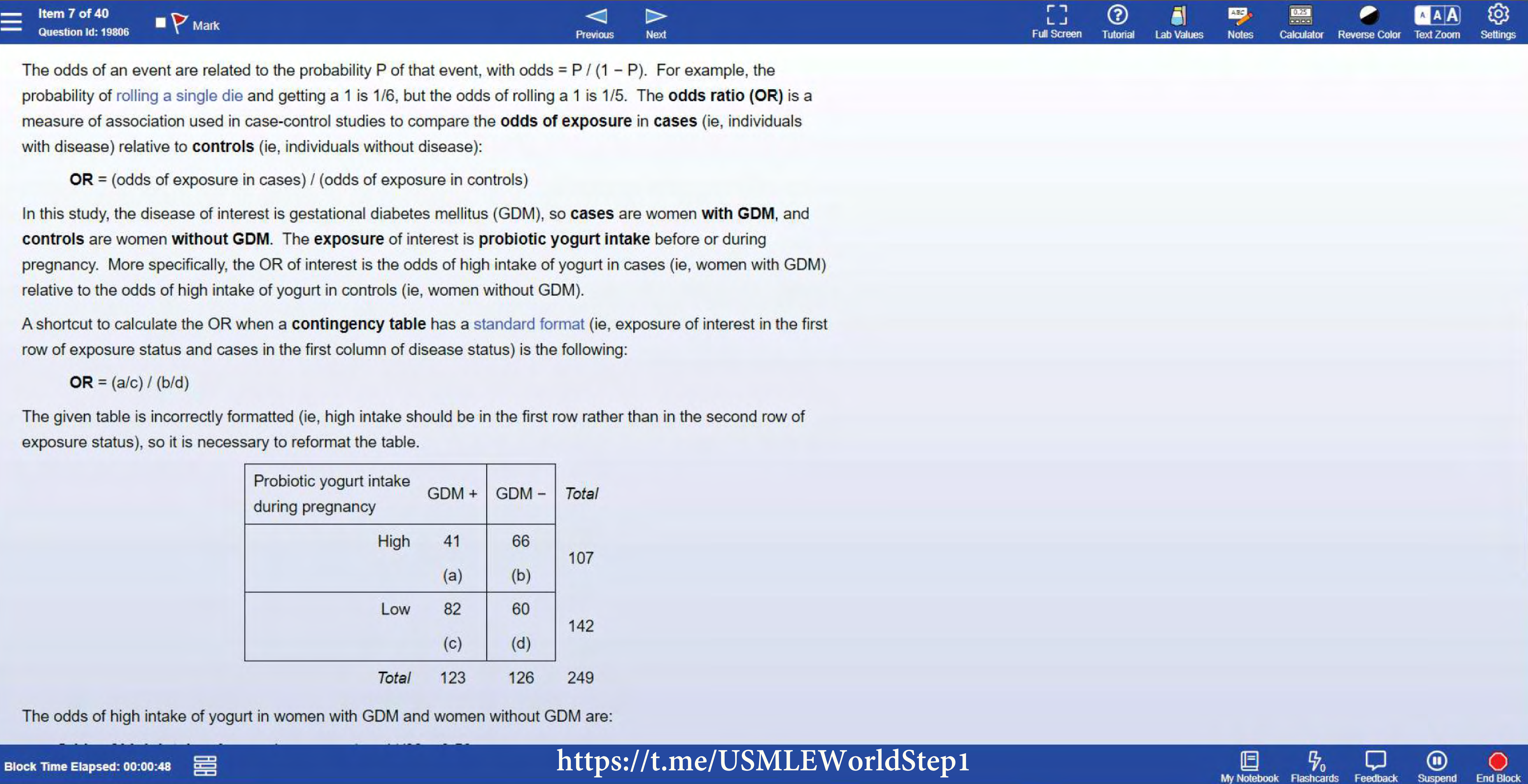
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The odds of an event are related to the probability P of that event, with odds = P / (1 − P). For example, the probability of rolling a single die and getting a 1 is 1/6, but the odds of rolling a 1 is 1/5. The **odds ratio (OR)** is a measure of association used in case-control studies to compare the **odds of exposure** in **cases** (ie, individuals with disease) relative to **controls** (ie, individuals without disease):

OR = (odds of exposure in cases) / (odds of exposure in controls)

In this study, the disease of interest is gestational diabetes mellitus (GDM), so **cases** are women **with GDM**, and **controls** are women **without GDM**. The **exposure** of interest is **probiotic yogurt intake** before or during pregnancy. More specifically, the OR of interest is the odds of high intake of yogurt in cases (ie, women with GDM) relative to the odds of high intake of yogurt in controls (ie, women without GDM).

A shortcut to calculate the OR when a **contingency table** has a standard format (ie, exposure of interest in the first row of exposure status and cases in the first column of disease status) is the following:

OR = (a/c) / (b/d)

The given table is incorrectly formatted (ie, high intake should be in the first row rather than in the second row of exposure status), so it is necessary to reformat the table.

Probiotic yogurt intake during pregnancy	GDM +	GDM −	*Total*
High	41 (a)	66 (b)	107
Low	82 (c)	60 (d)	142
Total	123	126	249

The odds of high intake of yogurt in women with GDM and women without GDM are:

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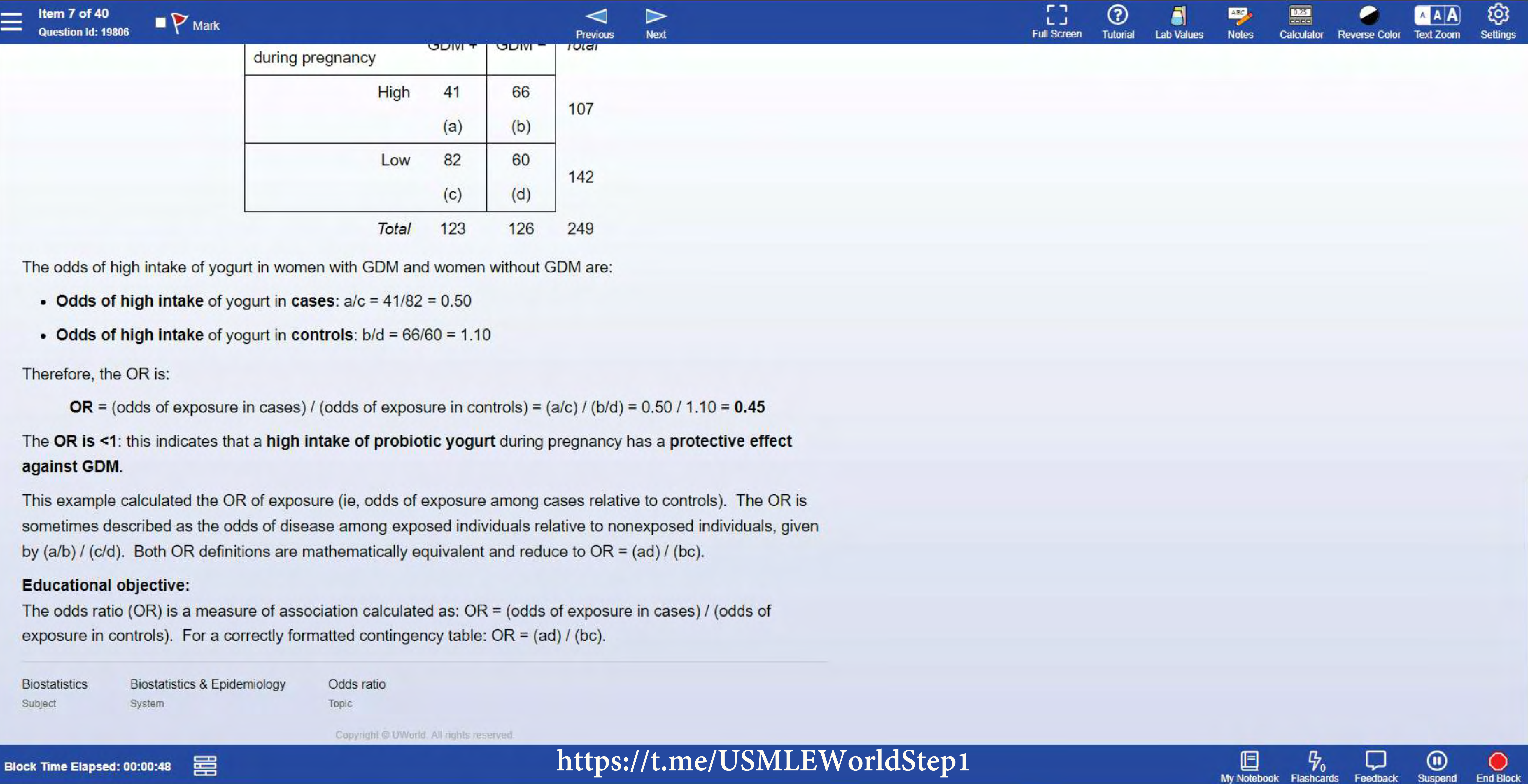
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during pregnancy	GDM +	GDM −	Total
High	41 (a)	66 (b)	107
Low	82 (c)	60 (d)	142
Total	123	126	249

The odds of high intake of yogurt in women with GDM and women without GDM are:

- **Odds of high intake** of yogurt in **cases**: a/c = 41/82 = 0.50
- **Odds of high intake** of yogurt in **controls**: b/d = 66/60 = 1.10

Therefore, the OR is:

OR = (odds of exposure in cases) / (odds of exposure in controls) = (a/c) / (b/d) = 0.50 / 1.10 = **0.45**

The **OR is <1**: this indicates that a **high intake of probiotic yogurt** during pregnancy has a **protective effect against GDM**.

This example calculated the OR of exposure (ie, odds of exposure among cases relative to controls). The OR is sometimes described as the odds of disease among exposed individuals relative to nonexposed individuals, given by (a/b) / (c/d). Both OR definitions are mathematically equivalent and reduce to OR = (ad) / (bc).

Educational objective:

The odds ratio (OR) is a measure of association calculated as: OR = (odds of exposure in cases) / (odds of exposure in controls). For a correctly formatted contingency table: OR = (ad) / (bc).

Biostatistics	Biostatistics & Epidemiology	Odds ratio
Subject	System	Topic

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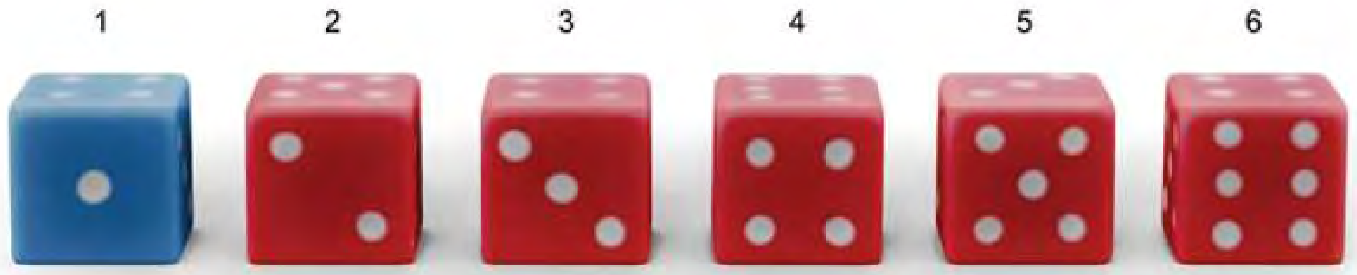

Probability of rolling 1: 1/6

Odds of rolling 1: (1/6) / (5/6) = 1/5

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(a)	(b)

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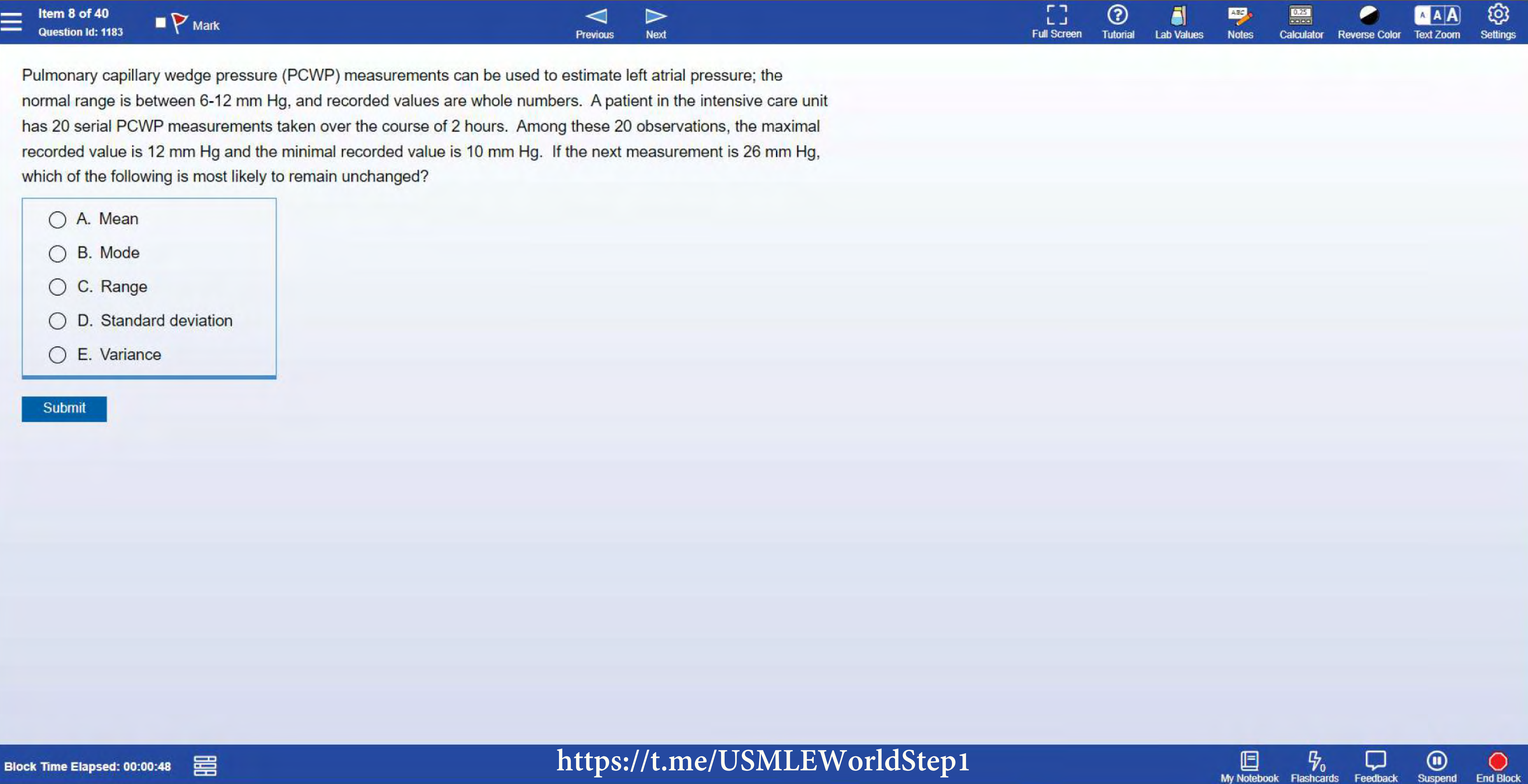
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Pulmonary capillary wedge pressure (PCWP) measurements can be used to estimate left atrial pressure; the normal range is between 6-12 mm Hg, and recorded values are whole numbers. A patient in the intensive care unit has 20 serial PCWP measurements taken over the course of 2 hours. Among these 20 observations, the maximal recorded value is 12 mm Hg and the minimal recorded value is 10 mm Hg. If the next measurement is 26 mm Hg, which of the following is most likely to remain unchanged?

- ○ A. Mean
- ○ B. Mode
- ○ C. Range
- ○ D. Standard deviation
- ○ E. Variance

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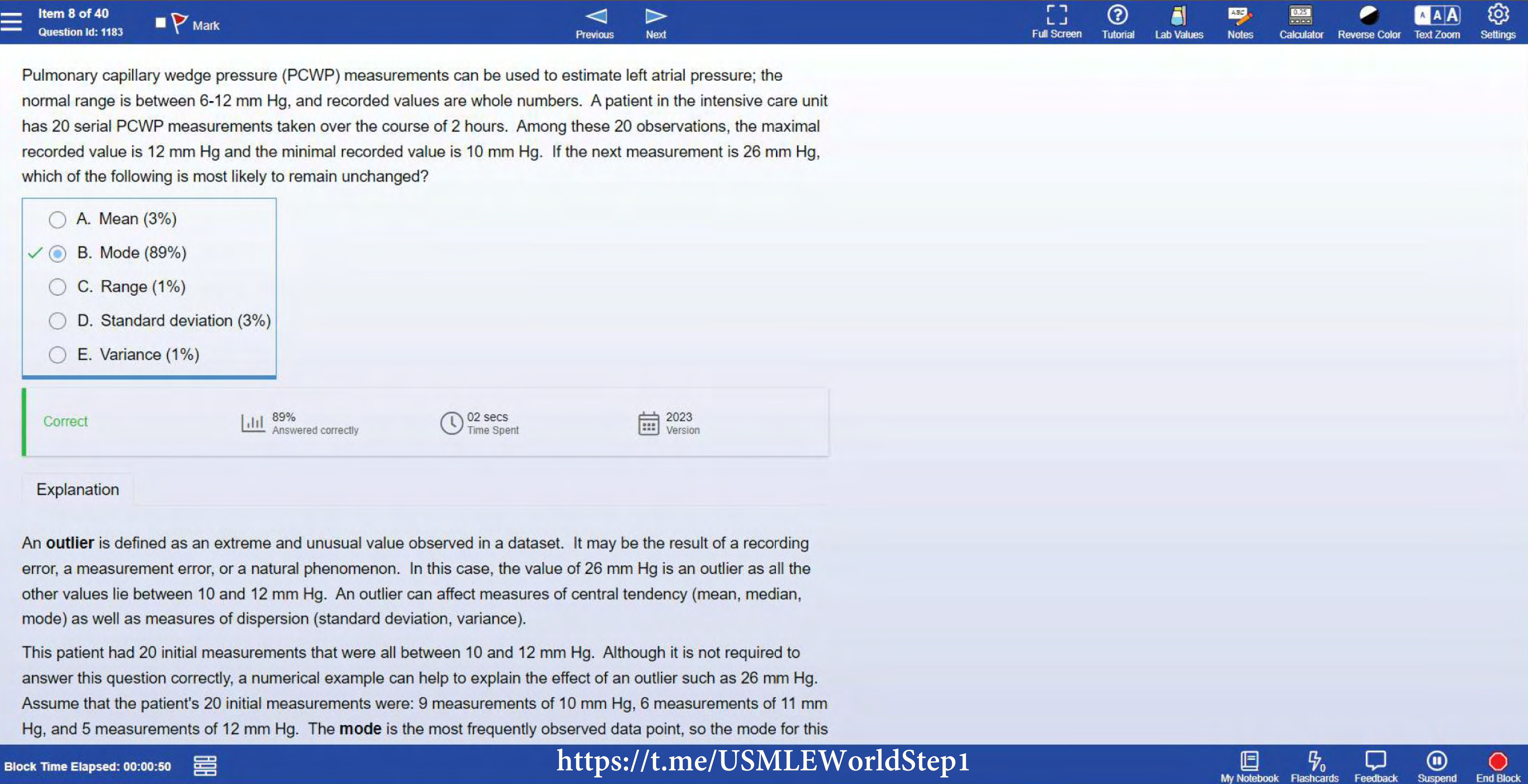
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Pulmonary capillary wedge pressure (PCWP) measurements can be used to estimate left atrial pressure; the normal range is between 6-12 mm Hg, and recorded values are whole numbers. A patient in the intensive care unit has 20 serial PCWP measurements taken over the course of 2 hours. Among these 20 observations, the maximal recorded value is 12 mm Hg and the minimal recorded value is 10 mm Hg. If the next measurement is 26 mm Hg, which of the following is most likely to remain unchanged?

○ A. Mean (3%)
✓ ● B. Mode (89%)
○ C. Range (1%)
○ D. Standard deviation (3%)
○ E. Variance (1%)

Correct
89% Answered correctly
02 secs Time Spent
2023 Version

Explanation

An **outlier** is defined as an extreme and unusual value observed in a dataset. It may be the result of a recording error, a measurement error, or a natural phenomenon. In this case, the value of 26 mm Hg is an outlier as all the other values lie between 10 and 12 mm Hg. An outlier can affect measures of central tendency (mean, median, mode) as well as measures of dispersion (standard deviation, variance).

This patient had 20 initial measurements that were all between 10 and 12 mm Hg. Although it is not required to answer this question correctly, a numerical example can help to explain the effect of an outlier such as 26 mm Hg. Assume that the patient's 20 initial measurements were: 9 measurements of 10 mm Hg, 6 measurements of 11 mm Hg, and 5 measurements of 12 mm Hg. The **mode** is the most frequently observed data point, so the mode for this

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Explanation

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This patient had 20 initial measurements that were all between 10 and 12 mm Hg. Although it is not required to answer this question correctly, a numerical example can help to explain the effect of an outlier such as 26 mm Hg. Assume that the patient's 20 initial measurements were: 9 measurements of 10 mm Hg, 6 measurements of 11 mm Hg, and 5 measurements of 12 mm Hg. The **mode** is the most frequently observed data point, so the mode for this initial dataset is 10 mm Hg (because this value is observed 9 times whereas the other 2 values are observed 6 times and 5 times). If the next measurement is 26 mm Hg, the mode would remain 10 mm Hg because this would still be the most commonly observed value. Therefore, the mode would remain unchanged. The mode tends to be resistant to outliers because outliers are not likely to affect the most frequently observed value in a dataset.

(Choice A) The **mean** (or average) can be quite sensitive to outliers, especially in the case of small datasets and extreme outliers. For instance, the mean of the 20 initial measurements is 10.8 mm Hg (obtained by calculating [9 × 10 mm Hg + 6 × 11 mm Hg + 5 × 12 mm Hg] / 20). With an additional measurement of 26 mm Hg, the mean would become 11.5 mm Hg (obtained by calculating [1 × 26 mm Hg + 9 × 10 mm Hg + 6 × 11 mm Hg + 5 × 12 mm Hg] / 21).

(Choice C) The **range** is equal to the maximal value minus the minimal value and would clearly be affected by outliers. With the 20 initial measurements, the range is 12 mm Hg – 10 mm Hg = 2 mm Hg. If the next measurement is 26 mm Hg, then the range will be 26 mm Hg – 10 mm Hg = 16 mm Hg.

(Choices D and E) The standard deviation and variance are measures of dispersion, which reflect how spread out the values in a dataset are from one another. The standard deviation and variance tend to be sensitive to outliers because outliers increase the dispersion of datasets.

Educational objective:

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This patient had 20 initial measurements that were all between 10 and 12 mm Hg. Although it is not required to answer this question correctly, a numerical example can help to explain the effect of an outlier such as 26 mm Hg. Assume that the patient's 20 initial measurements were: 9 measurements of 10 mm Hg, 6 measurements of 11 mm Hg, and 5 measurements of 12 mm Hg. The **mode** is the most frequently observed data point, so the mode for this initial dataset is 10 mm Hg (because this value is observed 9 times whereas the other 2 values are observed 6 times and 5 times). If the next measurement is 26 mm Hg, the mode would remain 10 mm Hg because this would still be the most commonly observed value. Therefore, the mode would remain unchanged. The mode tends to be resistant to outliers because outliers are not likely to affect the most frequently observed value in a dataset.

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(Choices D and E) The standard deviation and variance are measures of dispersion, which reflect how spread out the values in a dataset are from one another. The standard deviation and variance tend to be sensitive to outliers because outliers increase the dispersion of datasets.

Educational objective:

An outlier is defined as an extreme and unusual observed value in a dataset. It can affect measures of central tendency (mean, median, mode) as well as measures of dispersion (standard deviation, variance). Modes tend to be resistant to outliers.

Biostatistics	Biostatistics & Epidemiology	Central tendency (mean, median, mode, outliers)
Subject	System	Topic

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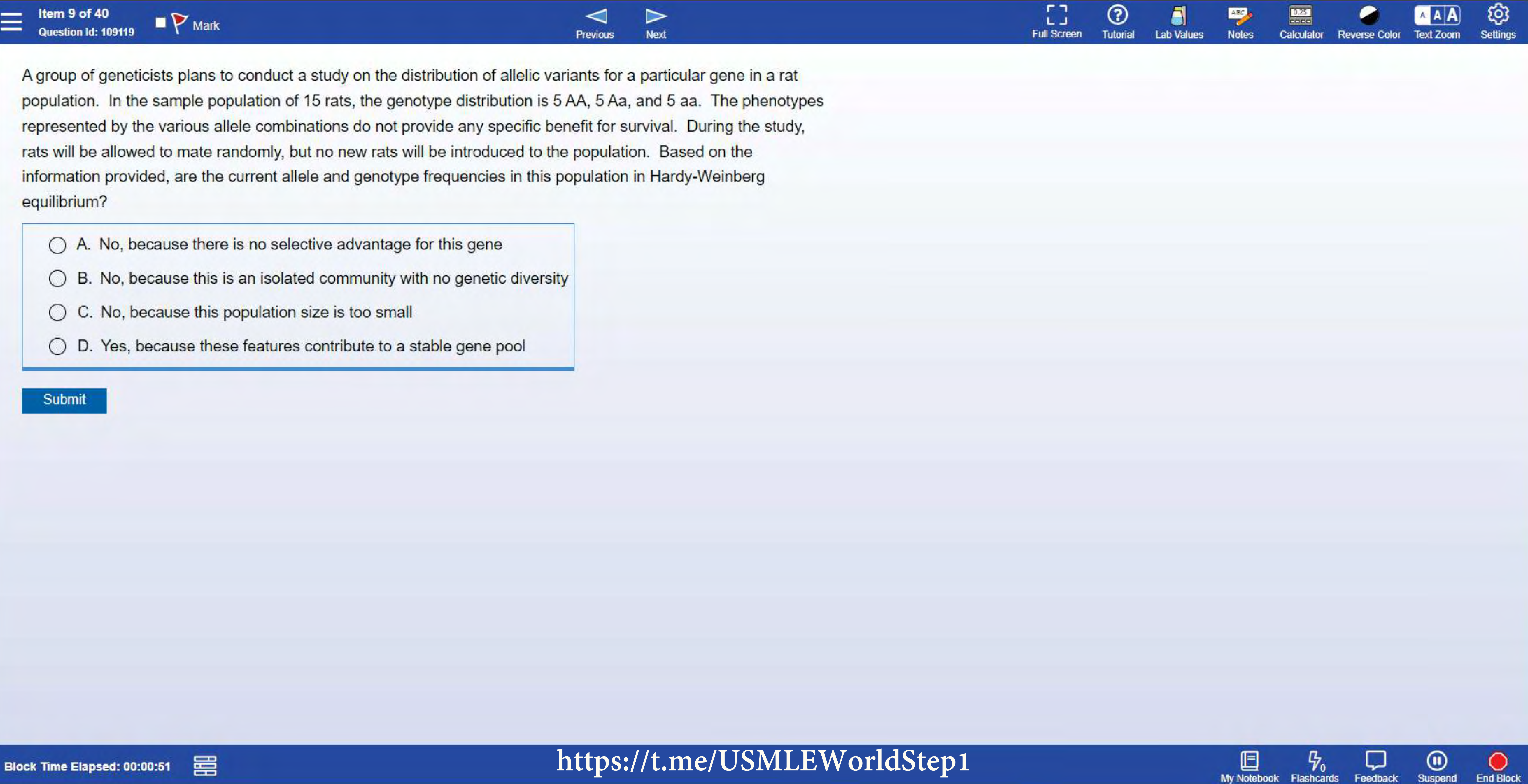
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A group of geneticists plans to conduct a study on the distribution of allelic variants for a particular gene in a rat population. In the sample population of 15 rats, the genotype distribution is 5 AA, 5 Aa, and 5 aa. The phenotypes represented by the various allele combinations do not provide any specific benefit for survival. During the study, rats will be allowed to mate randomly, but no new rats will be introduced to the population. Based on the information provided, are the current allele and genotype frequencies in this population in Hardy-Weinberg equilibrium?

○ A. No, because there is no selective advantage for this gene
○ B. No, because this is an isolated community with no genetic diversity
○ C. No, because this population size is too small
○ D. Yes, because these features contribute to a stable gene pool

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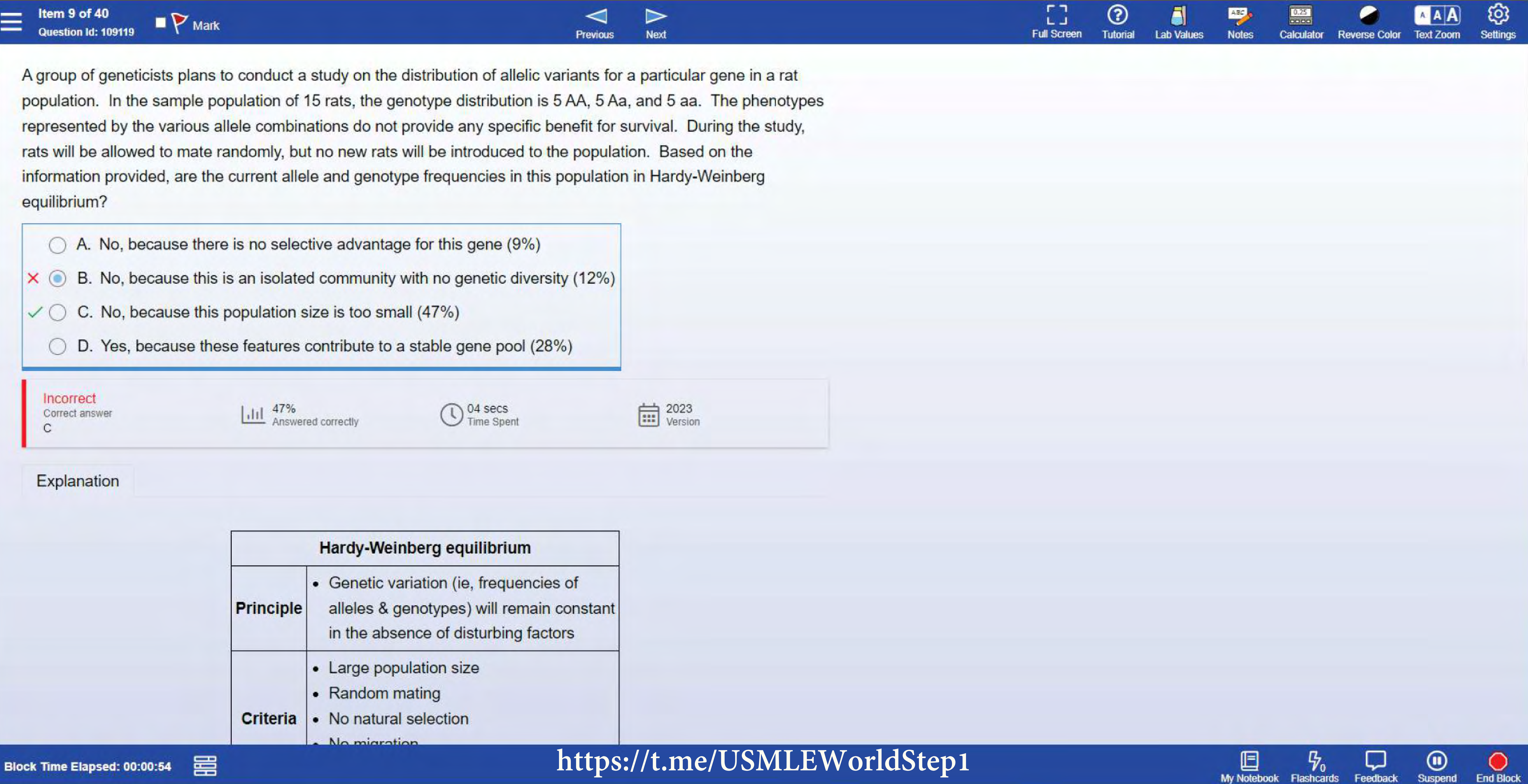
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○ A. No, because there is no selective advantage for this gene (9%)

✗ ● B. No, because this is an isolated community with no genetic diversity (12%)

✓ ○ C. No, because this population size is too small (47%)

○ D. Yes, because these features contribute to a stable gene pool (28%)

Incorrect
Correct answer
C

47%
Answered correctly

04 secs
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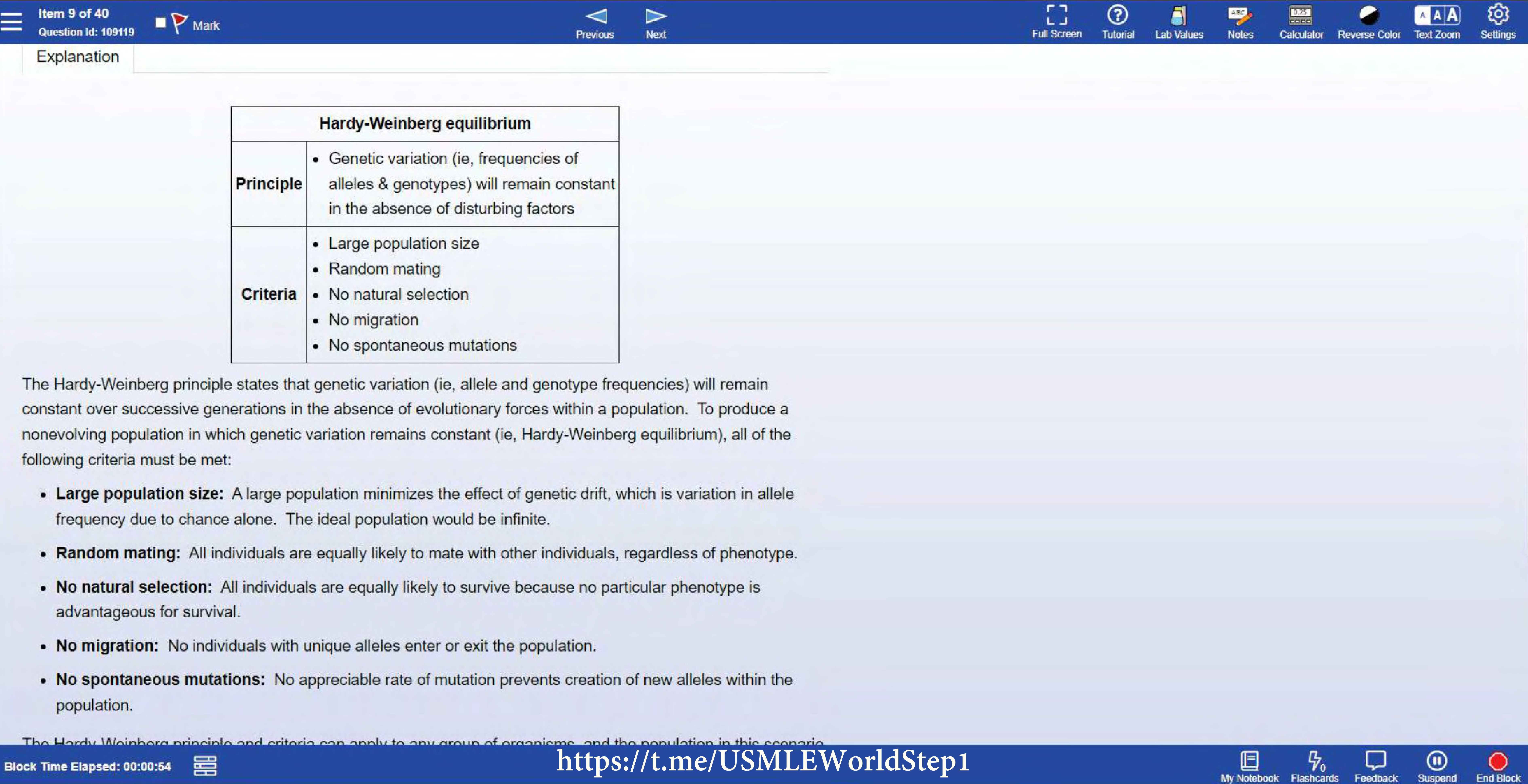
Explanation

Hardy-Weinberg equilibrium	
Principle	• Genetic variation (ie, frequencies of alleles & genotypes) will remain constant in the absence of disturbing factors
Criteria	• Large population size • Random mating • No natural selection • No migration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Hardy-Weinberg equilibrium	
Principle	Genetic variation (ie, frequencies of alleles & genotypes) will remain constant in the absence of disturbing factors
Criteria	Large population size Random mating No natural selection No migration No spontaneous mutations

The Hardy-Weinberg principle states that genetic variation (ie, allele and genotype frequencies) will remain constant over successive generations in the absence of evolutionary forces within a population. To produce a nonevolving population in which genetic variation remains constant (ie, Hardy-Weinberg equilibrium), all of the following criteria must be met:

- **Large population size:** A large population minimizes the effect of genetic drift, which is variation in allele frequency due to chance alone. The ideal population would be infinite.
- **Random mating:** All individuals are equally likely to mate with other individuals, regardless of phenotype.
- **No natural selection:** All individuals are equally likely to survive because no particular phenotype is advantageous for survival.
- **No migration:** No individuals with unique alleles enter or exit the population.
- **No spontaneous mutations:** No appreciable rate of mutation prevents creation of new alleles within the population.

The Hardy-Weinberg principle and criteria can apply to any group of organisms, and the population in this scenario

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	- No migration - No spontaneous mutations

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- **No natural selection:** All individuals are equally likely to survive because no particular phenotype is advantageous for survival.
- **No migration:** No individuals with unique alleles enter or exit the population.
- **No spontaneous mutations:** No appreciable rate of mutation prevents creation of new alleles within the population.

The Hardy-Weinberg principle and criteria can apply to any group of organisms, and the population in this scenario satisfies certain criteria: there is random mating, and there is no natural selection, or migration **(Choices A and B)**. However, with only 15 rats, the **population is small** and therefore does not satisfy all criteria for Hardy-Weinberg equilibrium. In contrast to large populations (ie, >1000 individuals), a small population will be significantly affected by genetic drift, resulting in changing frequencies of alleles over successive generations **(Choice D)**.

Educational objective:

A population is in Hardy-Weinberg equilibrium when the frequency of alleles at a particular locus remains constant over successive generations within that population. To satisfy all criteria for the equilibrium, there must be a large population size, random mating, no natural selection, no migration, and no spontaneous mutations.

The Hardy-Weinberg principle states that genetic variation (ie, allele and genotype frequencies) will remain constant over successive generations in the absence of evolutionary forces within a population. To produce a nonev

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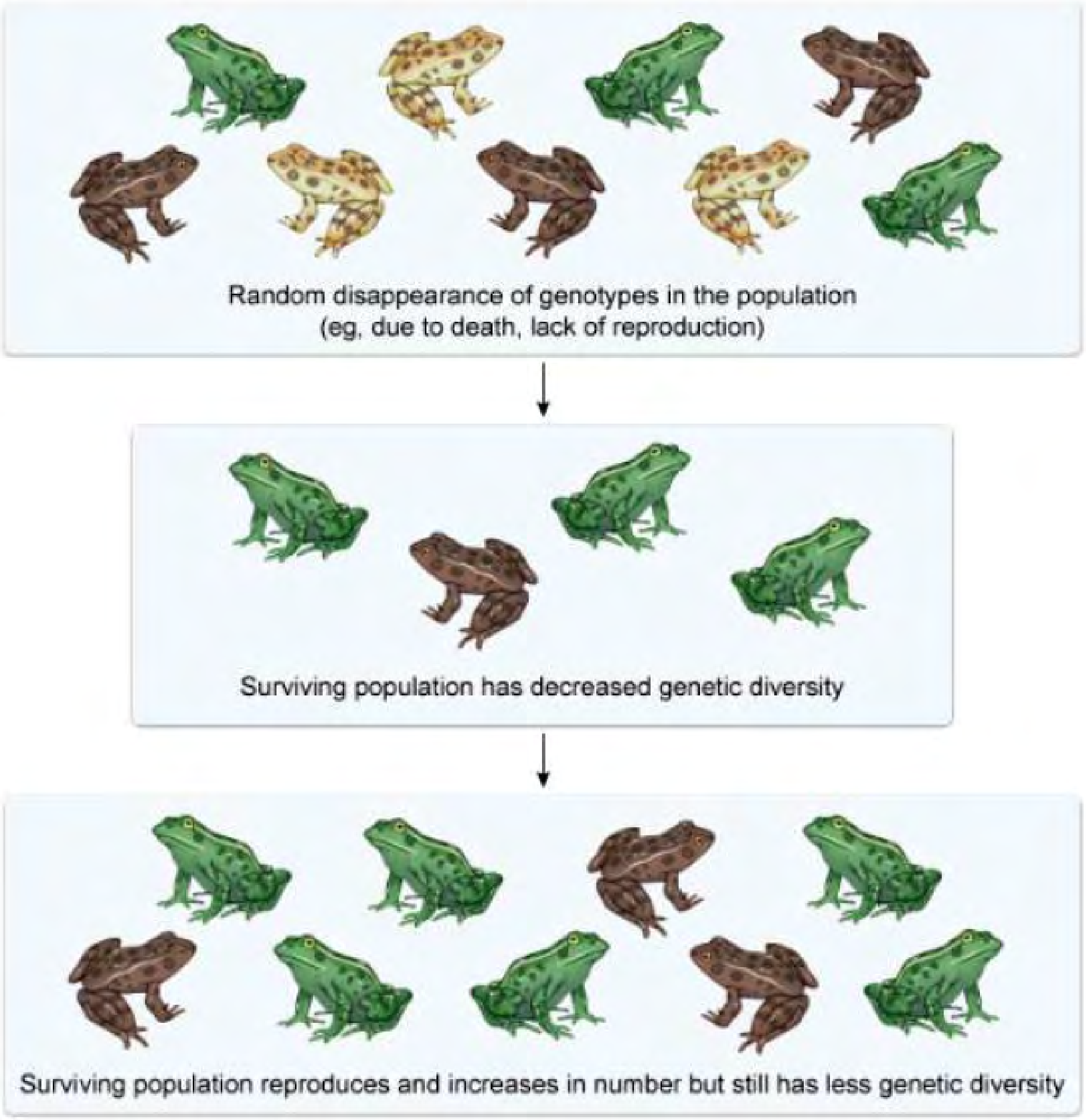
Genetic drift



Random disappearance of genotypes in the population (eg, due to death, lack of reproduction)

Surviving population has decreased genetic diversity

Surviving population reproduces and increases in number but still has less genetic diversity

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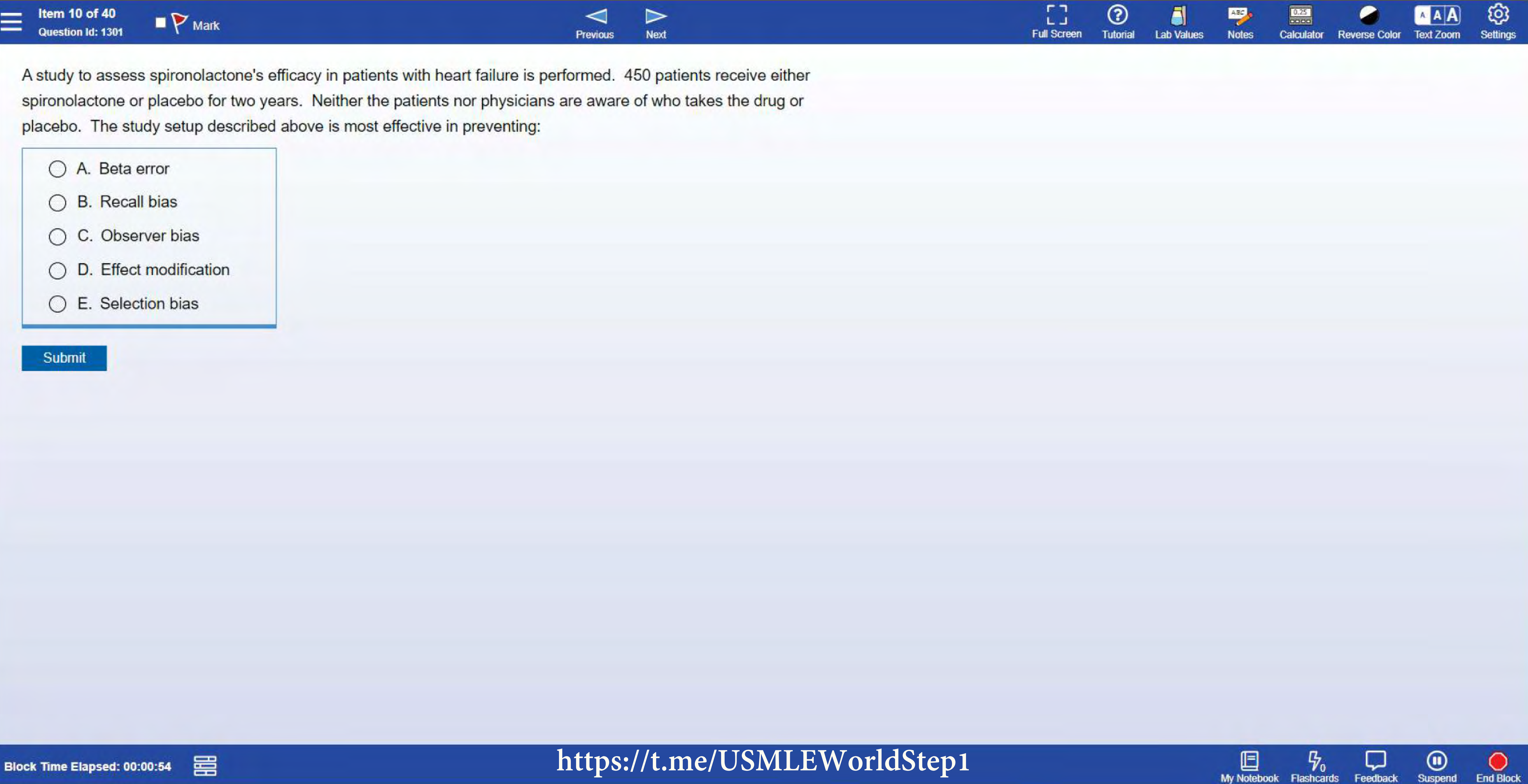
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Question Id: 1301

A study to assess spironolactone's efficacy in patients with heart failure is performed. 450 patients receive either spironolactone or placebo for two years. Neither the patients nor physicians are aware of who takes the drug or placebo. The study setup described above is most effective in preventing:

○ A. Beta error
○ B. Recall bias
○ C. Observer bias
○ D. Effect modification
○ E. Selection bias

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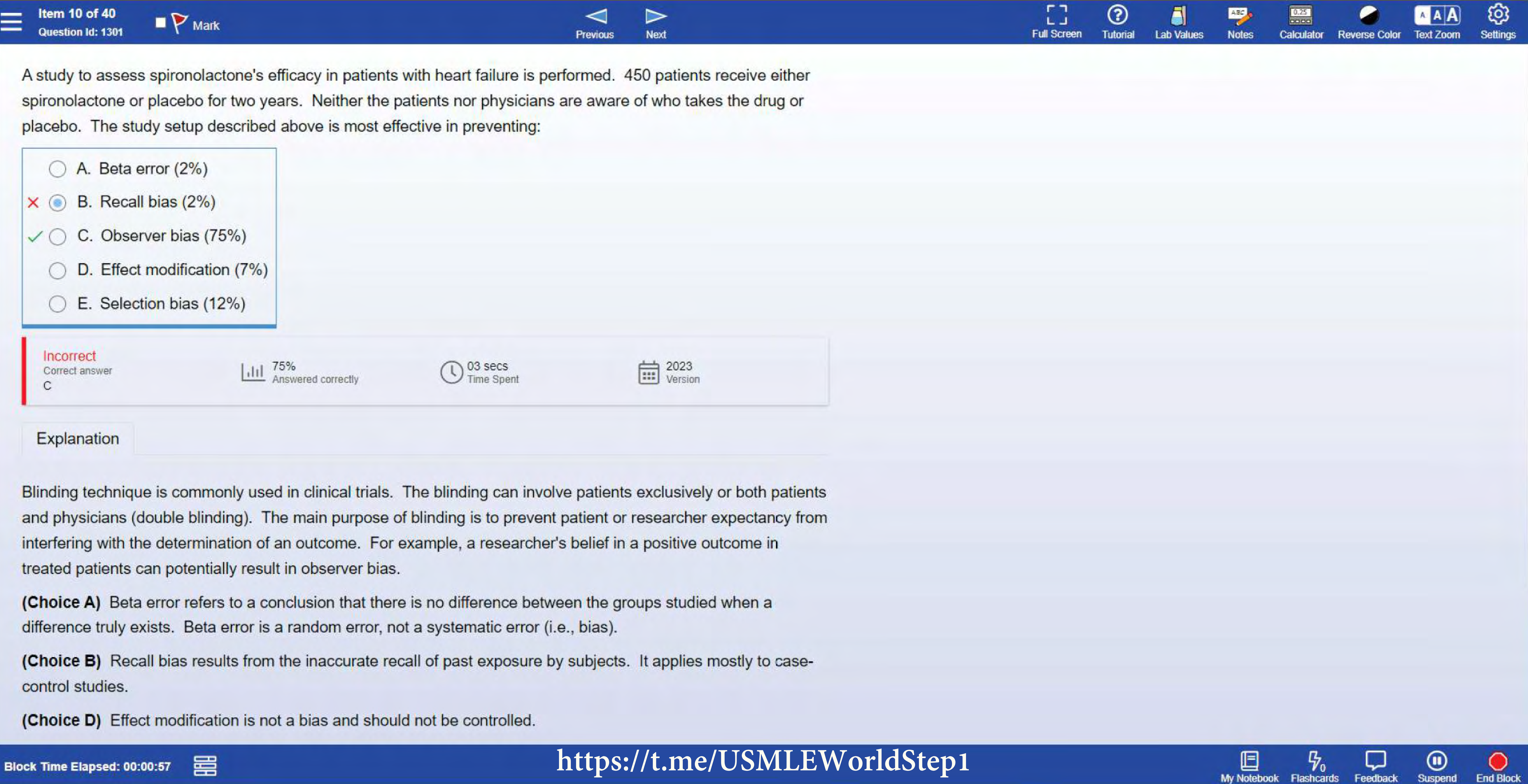
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A study to assess spironolactone's efficacy in patients with heart failure is performed. 450 patients receive either spironolactone or placebo for two years. Neither the patients nor physicians are aware of who takes the drug or placebo. The study setup described above is most effective in preventing:

- ○ A. Beta error (2%)
- ✗ ● B. Recall bias (2%)
- ✓ ○ C. Observer bias (75%)
- ○ D. Effect modification (7%)
- ○ E. Selection bias (12%)

Incorrect
Correct answer
C

75%
Answered correctly

03 secs
Time Spent

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Explanation

Blinding technique is commonly used in clinical trials. The blinding can involve patients exclusively or both patients and physicians (double blinding). The main purpose of blinding is to prevent patient or researcher expectancy from interfering with the determination of an outcome. For example, a researcher's belief in a positive outcome in treated patients can potentially result in observer bias.

(Choice A) Beta error refers to a conclusion that there is no difference between the groups studied when a difference truly exists. Beta error is a random error, not a systematic error (i.e., bias).

(Choice B) Recall bias results from the inaccurate recall of past exposure by subjects. It applies mostly to case-control studies.

(Choice D) Effect modification is not a bias and should not be controlled.

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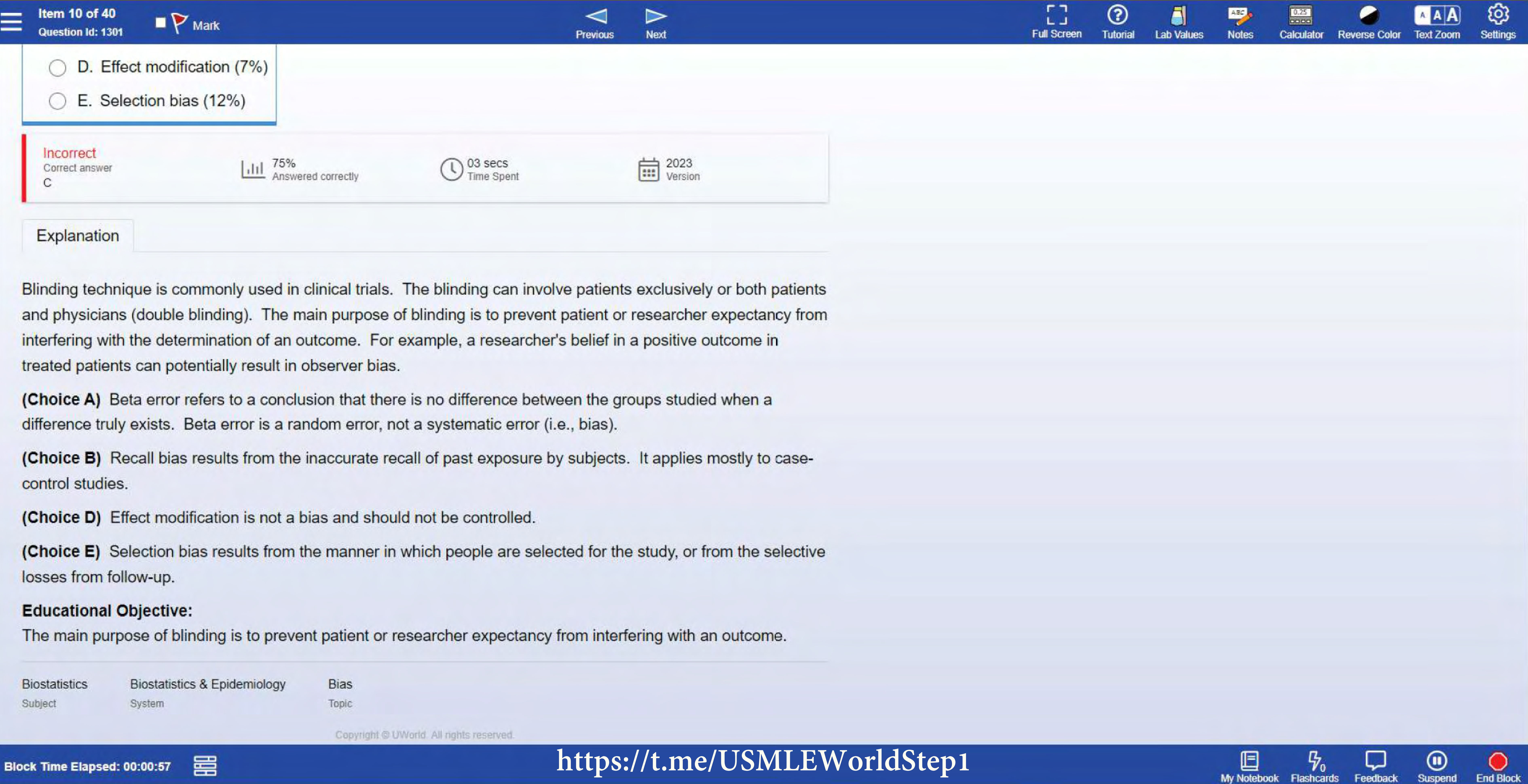
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○ D. Effect modification (7%)

○ E. Selection bias (12%)

Incorrect
Correct answer
C

75%
Answered correctly

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Explanation

Blinding technique is commonly used in clinical trials. The blinding can involve patients exclusively or both patients and physicians (double blinding). The main purpose of blinding is to prevent patient or researcher expectancy from interfering with the determination of an outcome. For example, a researcher's belief in a positive outcome in treated patients can potentially result in observer bias.

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(Choice B) Recall bias results from the inaccurate recall of past exposure by subjects. It applies mostly to case-control studies.

(Choice D) Effect modification is not a bias and should not be controlled.

(Choice E) Selection bias results from the manner in which people are selected for the study, or from the selective losses from follow-up.

Educational Objective:
The main purpose of blinding is to prevent patient or researcher expectancy from interfering with an outcome.

Biostatistics	Biostatistics & Epidemiology	Bias
Subject	System	Topic

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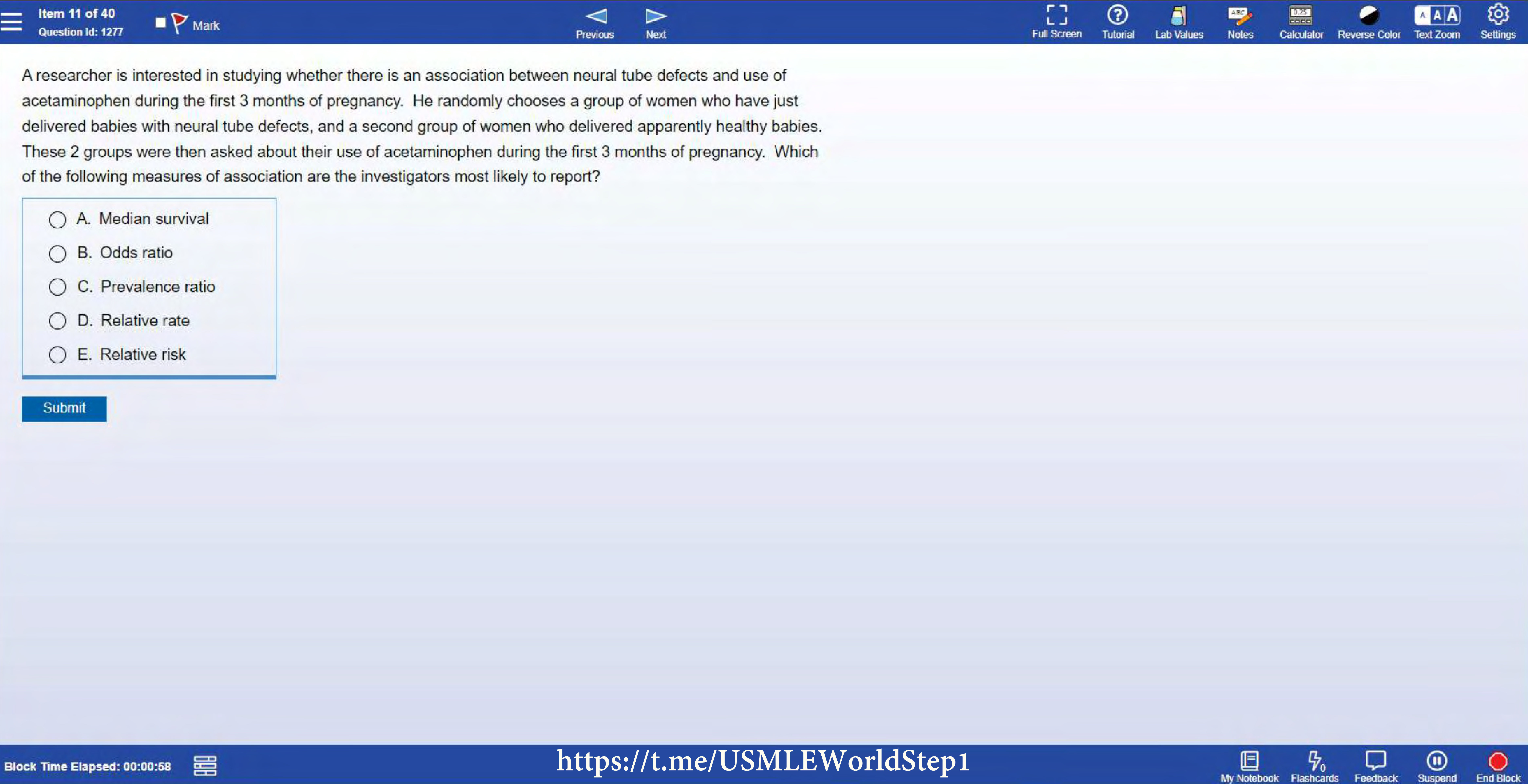
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A researcher is interested in studying whether there is an association between neural tube defects and use of acetaminophen during the first 3 months of pregnancy. He randomly chooses a group of women who have just delivered babies with neural tube defects, and a second group of women who delivered apparently healthy babies. These 2 groups were then asked about their use of acetaminophen during the first 3 months of pregnancy. Which of the following measures of association are the investigators most likely to report?

○ A. Median survival
○ B. Odds ratio
○ C. Prevalence ratio
○ D. Relative rate
○ E. Relative risk

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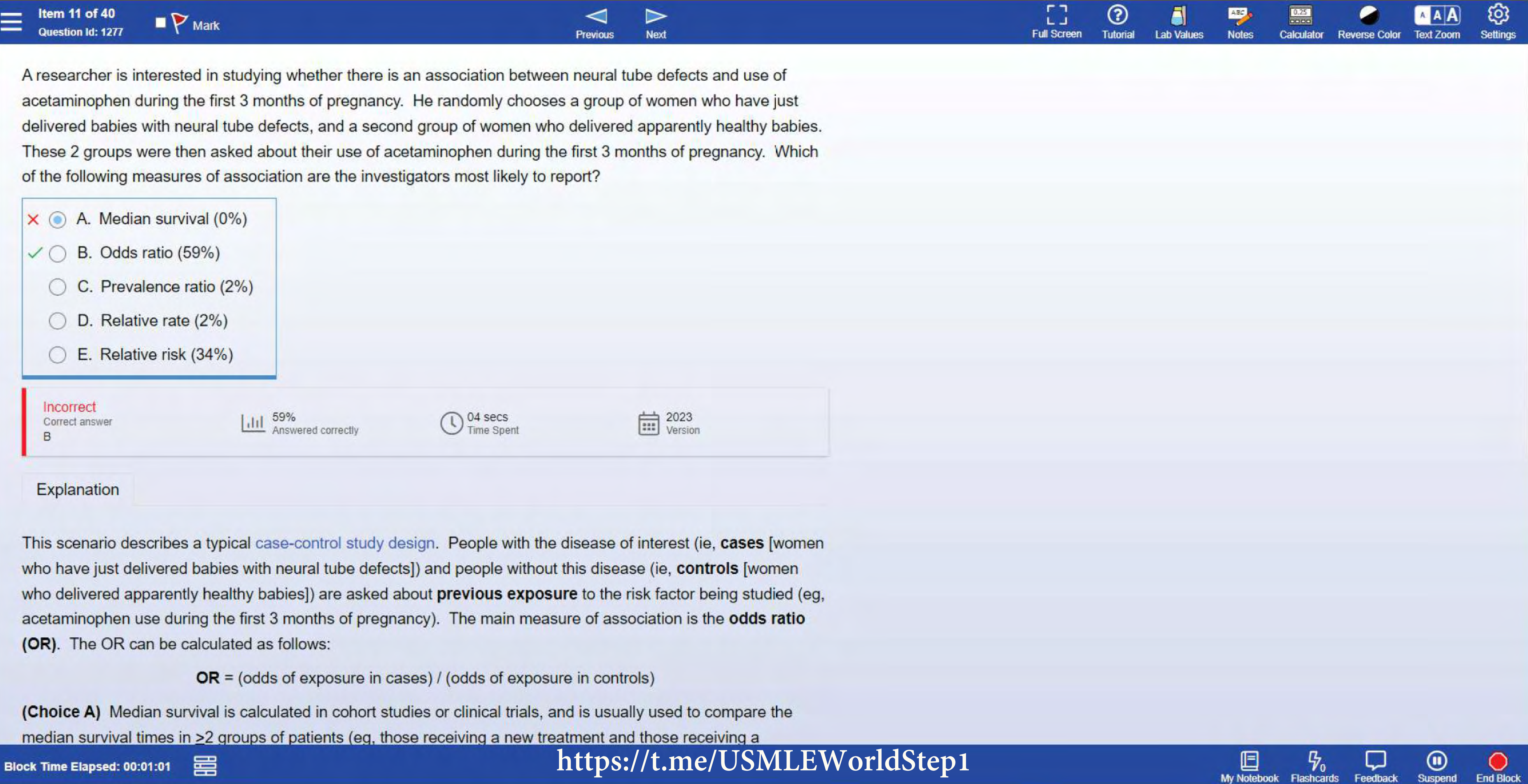
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- ✗ ● A. Median survival (0%)
- ✓ ○ B. Odds ratio (59%)
- ○ C. Prevalence ratio (2%)
- ○ D. Relative rate (2%)
- ○ E. Relative risk (34%)

Incorrect
Correct answer
B

59%
Answered correctly

04 secs
Time Spent

2023
Version

Explanation

This scenario describes a typical case-control study design. People with the disease of interest (ie, **cases** [women who have just delivered babies with neural tube defects]) and people without this disease (ie, **controls** [women who delivered apparently healthy babies]) are asked about **previous exposure** to the risk factor being studied (eg, acetaminophen use during the first 3 months of pregnancy). The main measure of association is the **odds ratio (OR)**. The OR can be calculated as follows:

OR = (odds of exposure in cases) / (odds of exposure in controls)

(Choice A) Median survival is calculated in cohort studies or clinical trials, and is usually used to compare the median survival times in $\geq$2 groups of patients (eg, those receiving a new treatment and those receiving a

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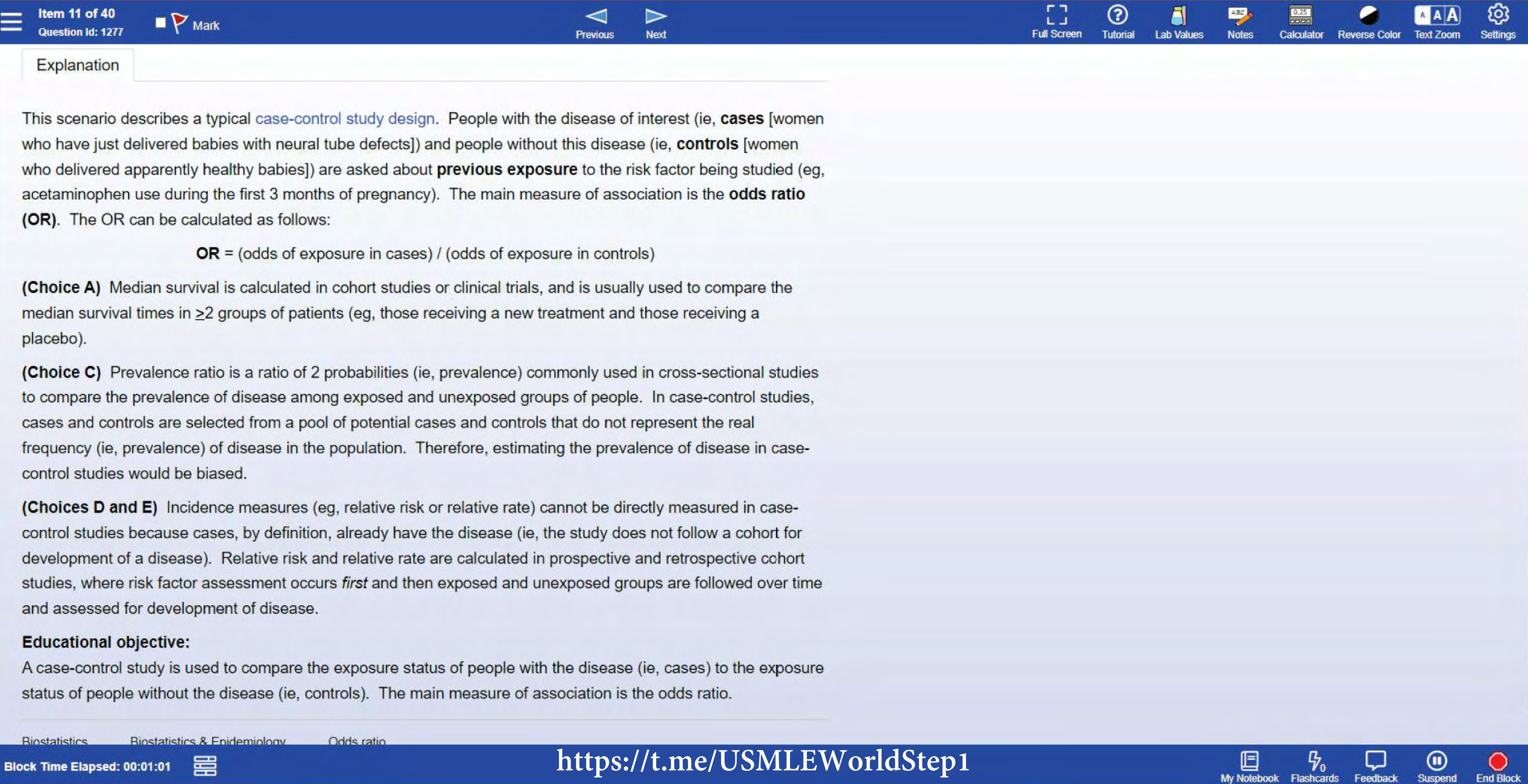
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Explanation

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OR = (odds of exposure in cases) / (odds of exposure in controls)

(Choice A) Median survival is calculated in cohort studies or clinical trials, and is usually used to compare the median survival times in $\geq$2 groups of patients (eg, those receiving a new treatment and those receiving a placebo).

(Choice C) Prevalence ratio is a ratio of 2 probabilities (ie, prevalence) commonly used in cross-sectional studies to compare the prevalence of disease among exposed and unexposed groups of people. In case-control studies, cases and controls are selected from a pool of potential cases and controls that do not represent the real frequency (ie, prevalence) of disease in the population. Therefore, estimating the prevalence of disease in case-control studies would be biased.

(Choices D and E) Incidence measures (eg, relative risk or relative rate) cannot be directly measured in case-control studies because cases, by definition, already have the disease (ie, the study does not follow a cohort for development of a disease). Relative risk and relative rate are calculated in prospective and retrospective cohort studies, where risk factor assessment occurs *first* and then exposed and unexposed groups are followed over time and assessed for development of disease.

Educational objective:

A case-control study is used to compare the exposure status of people with the disease (ie, cases) to the exposure status of people without the disease (ie, controls). The main measure of association is the odds ratio.

Biostatistics Biostatistics & Epidemiology Odds ratio

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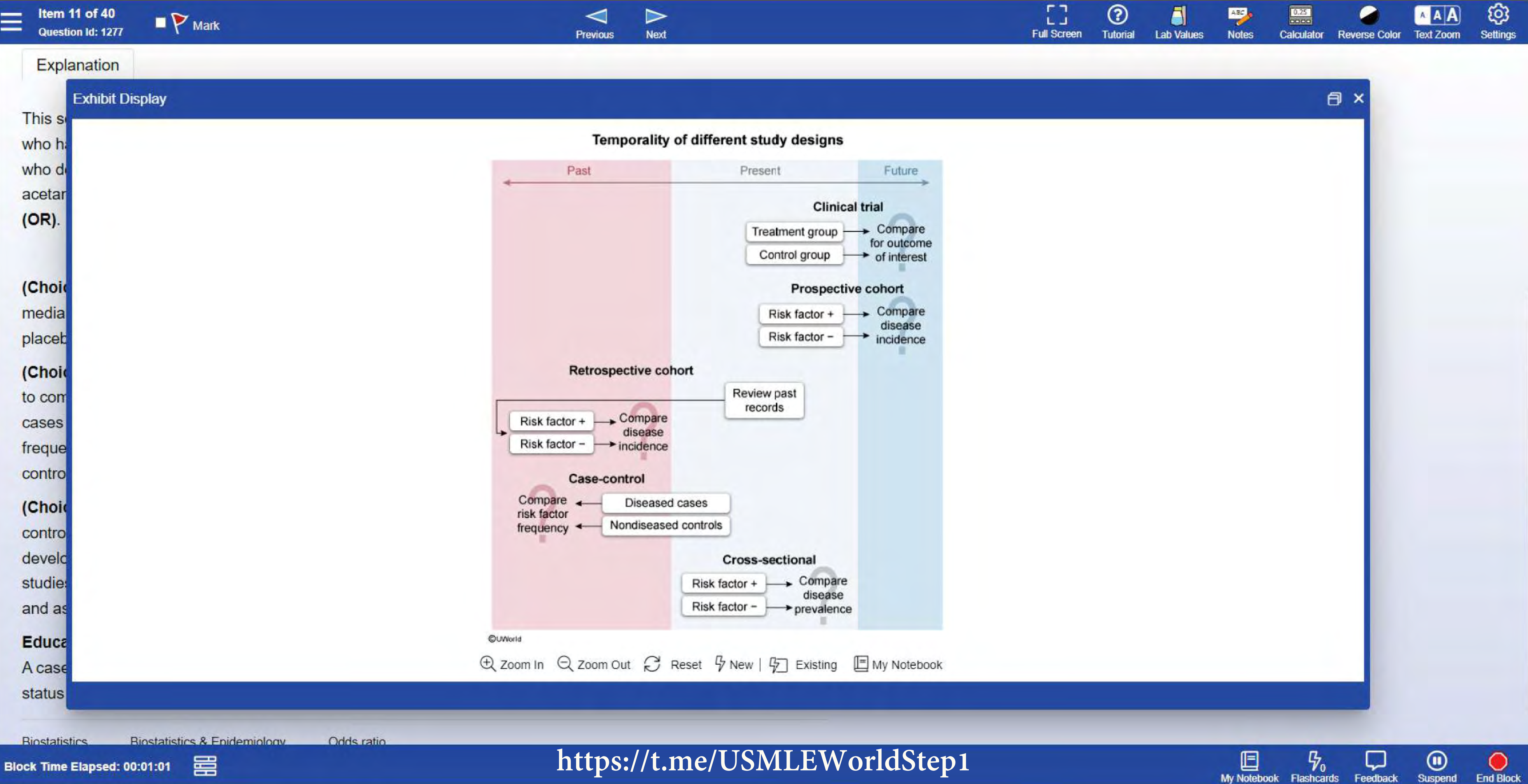
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Retrospective cohort
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Compare risk factor frequency
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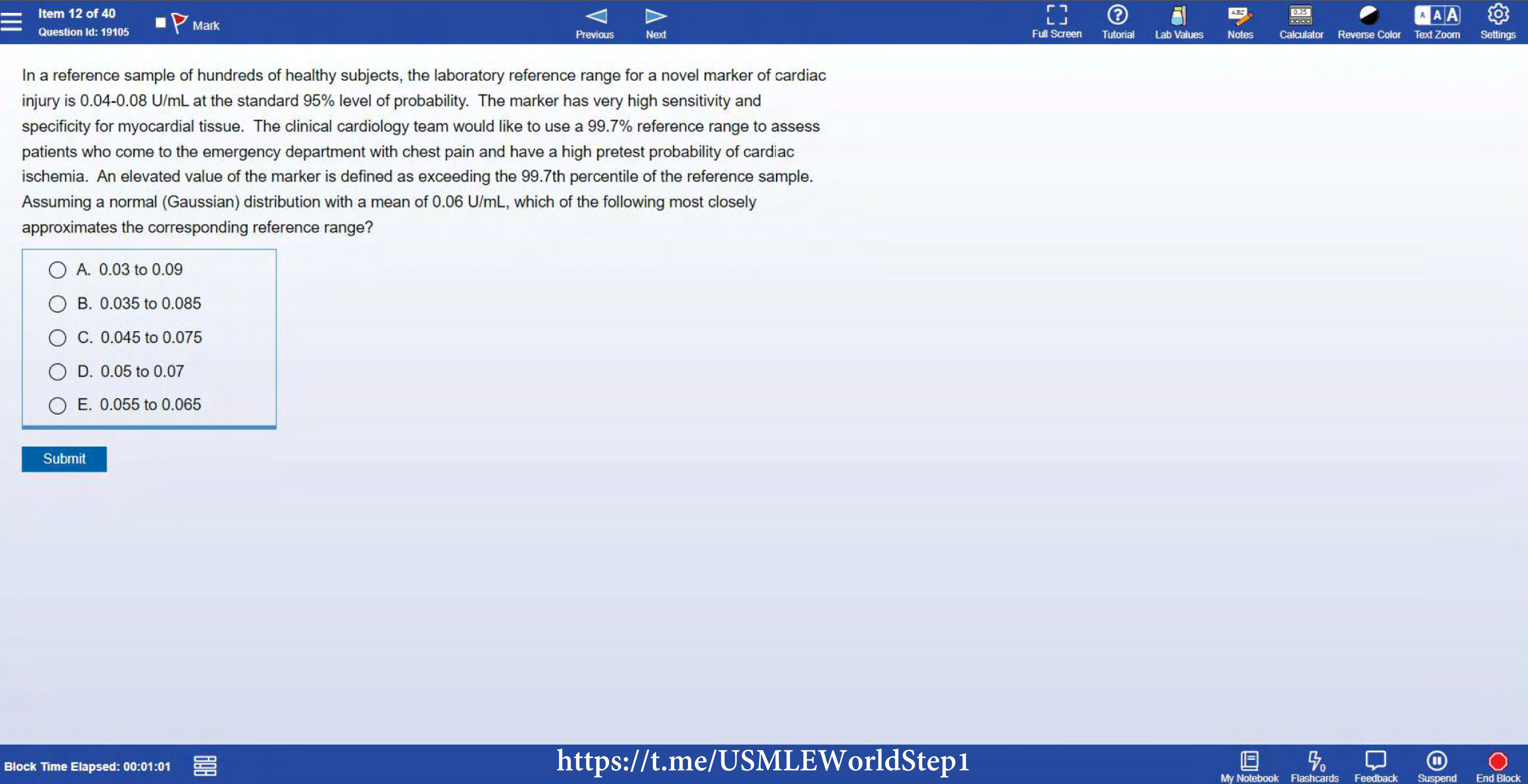
Temporality of different study designs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In a reference sample of hundreds of healthy subjects, the laboratory reference range for a novel marker of cardiac injury is 0.04-0.08 U/mL at the standard 95% level of probability. The marker has very high sensitivity and specificity for myocardial tissue. The clinical cardiology team would like to use a 99.7% reference range to assess patients who come to the emergency department with chest pain and have a high pretest probability of cardiac ischemia. An elevated value of the marker is defined as exceeding the 99.7th percentile of the reference sample. Assuming a normal (Gaussian) distribution with a mean of 0.06 U/mL, which of the following most closely approximates the corresponding reference range?

- ○ A. 0.03 to 0.09
- ○ B. 0.035 to 0.085
- ○ C. 0.045 to 0.075
- ○ D. 0.05 to 0.07
- ○ E. 0.055 to 0.065

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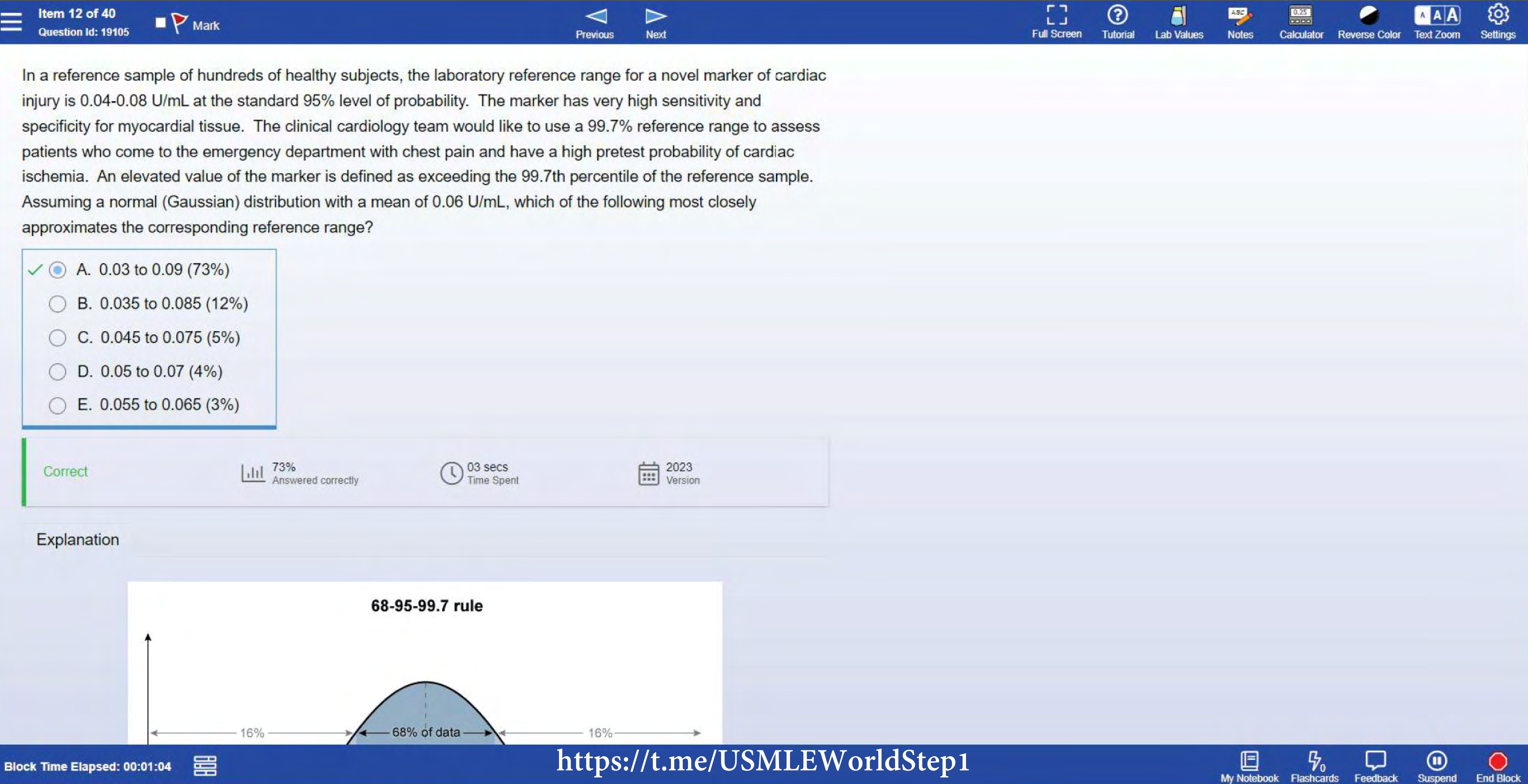
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- ✓ ● A. 0.03 to 0.09 (73%)
- ○ B. 0.035 to 0.085 (12%)
- ○ C. 0.045 to 0.075 (5%)
- ○ D. 0.05 to 0.07 (4%)
- ○ E. 0.055 to 0.065 (3%)

Correct

73% Answered correctly

03 secs Time Spent

2023 Version

Explanation

68-95-99.7 rule

16%
68% of data
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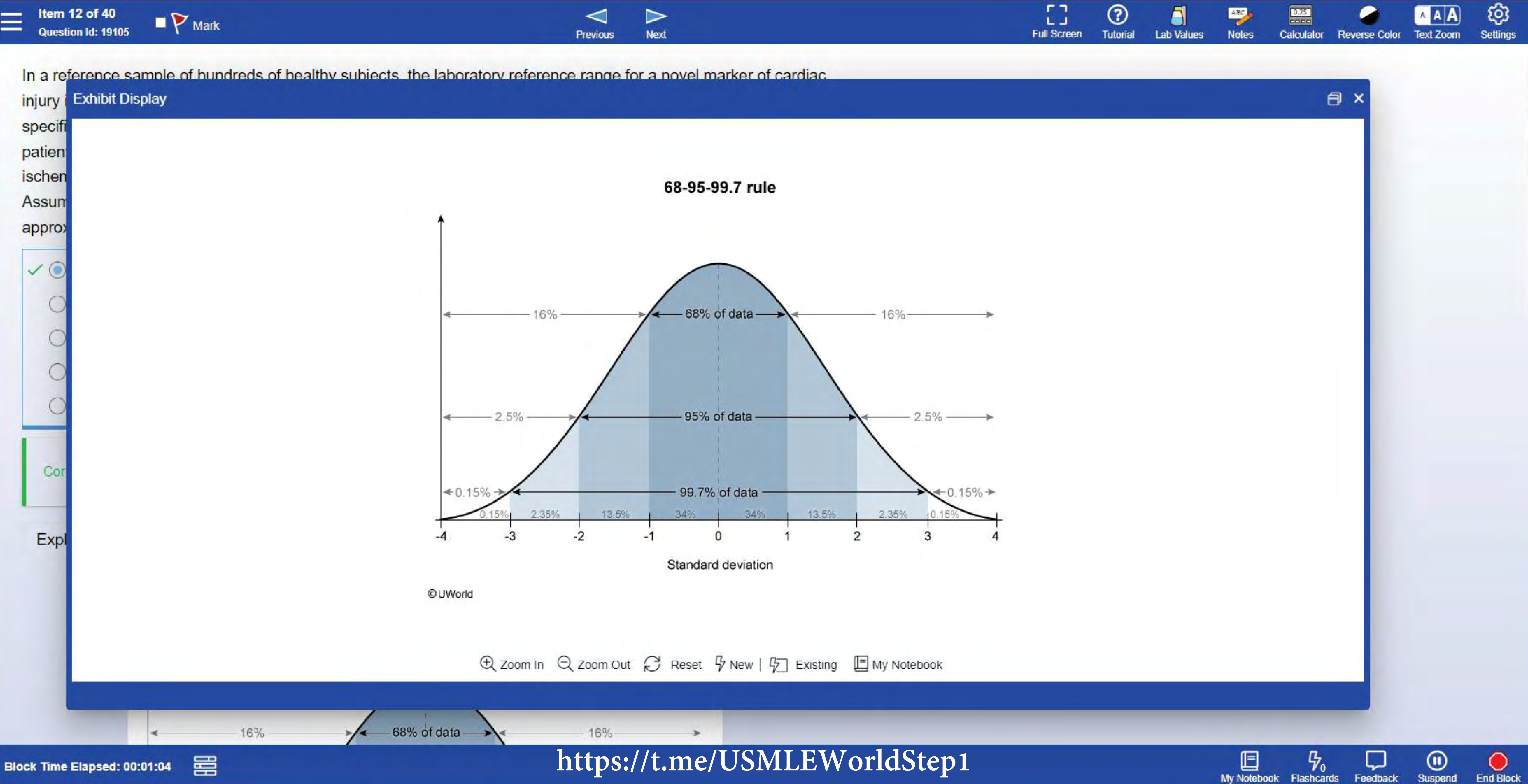
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In a reference sample of hundreds of healthy subjects, the laboratory reference range for a novel marker of cardiac
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68-95-99.7 rule

16%
68% of data
16%
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95% of data
2.5%
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99.7% of data
0.15%
0.15%
2.35%
13.5%
34%
34%
13.5%
2.35%
0.15%
-4
-3
-2
-1
0
1
2
3
4
Standard deviation

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New
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My Notebook
16%
68% of data
16%

Block Time Elapsed: 00:01:04

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Standard deviation
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A **normal (Gaussian) distribution** refers to a symmetrical, bell-shaped distribution with a fixed proportion of observations lying within a certain distance of the mean. This distance is called the **standard deviation (SD)** and reflects the **degree of dispersion** from the mean. According to the properties of this distribution, 68% of observations lie within 1 SD from the mean, with half (ie, 68/2 = 34%) above and half (34%) below the mean. The remaining 32% (= 100% − 68%) lie outside 1 SD from the mean, with half (ie, 32/2 = 16%) above and the other half (16%) below 1 SD from the mean. In addition, 95% of all observations lie within 2 SD of the mean, and 99.7% of all observations lie within 3 SD from the mean. This is the **68-95-99.7 rule**.

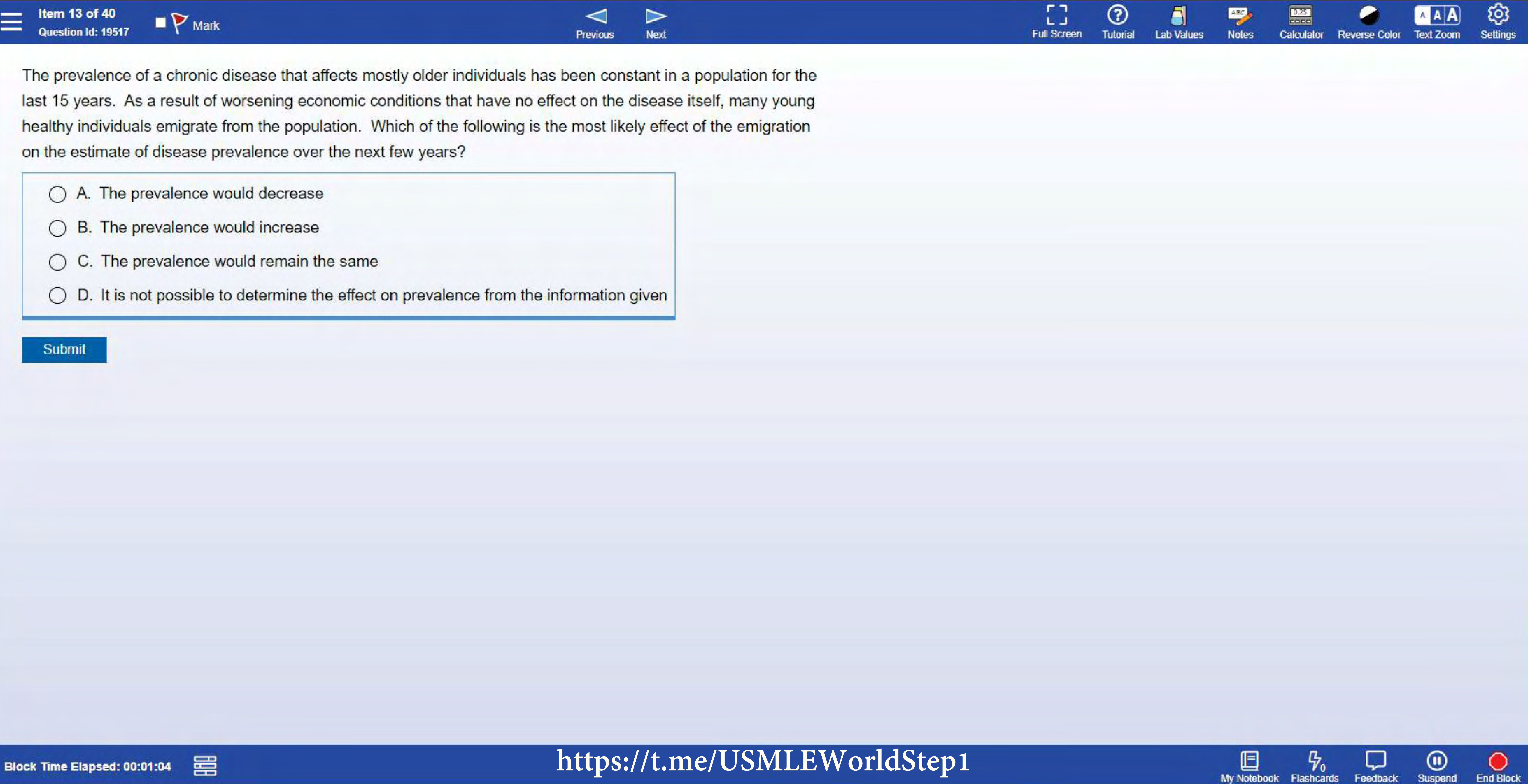
The 95% range for this marker with a **mean of 0.06** U/mL is 0.04 to 0.08 U/mL; given a normal distribution, this represents the range given by mean ± 2 SD. Therefore, **1 SD = 0.01** (because 0.04 = mean − 2 SD = 0.06 − 2 SD = 0.06 − 2 × 0.01 and, similarly, 0.08 = 0.06 + 2 × 0.01). The **99.7% range** is given by **mean ± 3 SD**; therefore, the 99.7% range is **0.03** (= mean − 3 SD = 0.06 − 3 × 0.01) to **0.09** (= mean + 3 SD = 0.06 + 3 × 0.01). Any result that falls outside this range (eg, a value exceeding this range) indicates that the value is different from what is seen in 99.7% of the reference population.

In laboratory measurements, although 95% is often used as a reference range, a 99% range is used in certain cases (eg, to determine cutoff for troponin in acute myocardial infarction). Other laboratory analysis methods involve performing more specific calculations when it is important to detect a difference in one direction (eg, for a cancer marker, knowing that the value is significantly higher than normal is more important than knowing that it is significantly different—either higher or lower—than normal). In some cases, high-sensitivity assays (eg, high-sensitivity C-reactive protein testing) allow the detection of values in the lower range of normal, which would not have been possible with standard assays.

Educational objective:

In a normal (bell-shaped) distribution, 68% of all values are within 1 standard deviation (SD) from the mean; 95% are within 2 SD from the mean; and 99.7% are within 3 SD from the mean.

References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The prevalence of a chronic disease that affects mostly older individuals has been constant in a population for the last 15 years. As a result of worsening economic conditions that have no effect on the disease itself, many young healthy individuals emigrate from the population. Which of the following is the most likely effect of the emigration on the estimate of disease prevalence over the next few years?

○ A. The prevalence would decrease
○ B. The prevalence would increase
○ C. The prevalence would remain the same
○ D. It is not possible to determine the effect on prevalence from the information given

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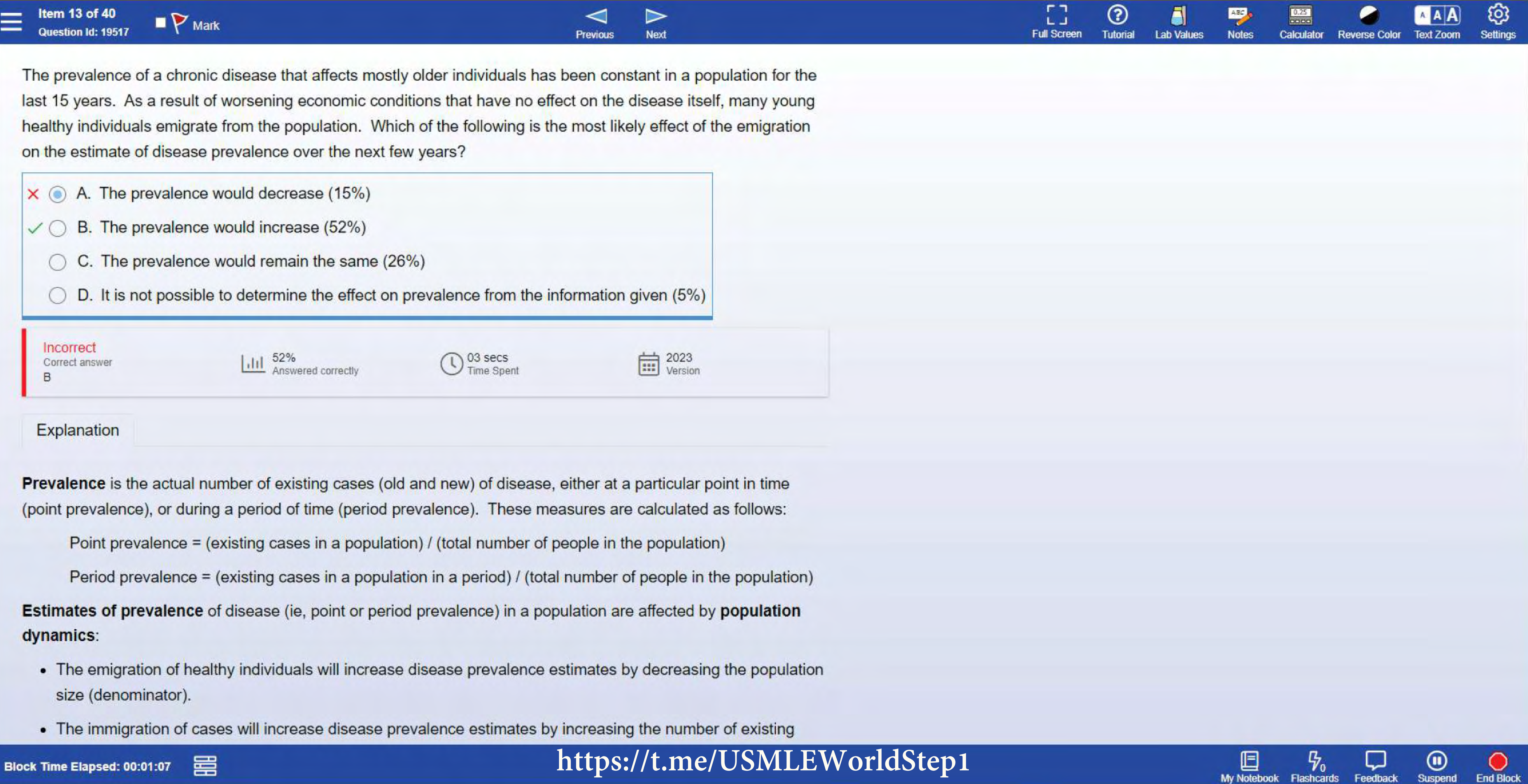
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✗ ● A. The prevalence would decrease (15%)

✓ ○ B. The prevalence would increase (52%)

○ C. The prevalence would remain the same (26%)

○ D. It is not possible to determine the effect on prevalence from the information given (5%)

Incorrect
Correct answer
B

52%
Answered correctly

03 secs
Time Spent

2023
Version

Explanation

Prevalence is the actual number of existing cases (old and new) of disease, either at a particular point in time (point prevalence), or during a period of time (period prevalence). These measures are calculated as follows:

Point prevalence = (existing cases in a population) / (total number of people in the population)

Period prevalence = (existing cases in a population in a period) / (total number of people in the population)

Estimates of prevalence of disease (ie, point or period prevalence) in a population are affected by **population dynamics**:

- The emigration of healthy individuals will increase disease prevalence estimates by decreasing the population size (denominator).
- The immigration of cases will increase disease prevalence estimates by increasing the number of existing

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Prevalence is the actual number of existing cases (old and new) of disease, either at a particular point in time (point prevalence), or during a period of time (period prevalence). These measures are calculated as follows:

Point prevalence = (existing cases in a population) / (total number of people in the population)

Period prevalence = (existing cases in a population in a period) / (total number of people in the population)

Estimates of prevalence of disease (ie, point or period prevalence) in a population are affected by **population dynamics**:

- The emigration of healthy individuals will increase disease prevalence estimates by decreasing the population size (denominator).
- The immigration of cases will increase disease prevalence estimates by increasing the number of existing cases (numerator).
- The emigration of cases will decrease disease prevalence estimates by decreasing the number of existing cases (numerator).
- The immigration of healthy individuals will decrease disease prevalence estimates by increasing the population size (denominator).

In this example, the prevalence of a chronic disease has been constant for the last 15 years; therefore, new cases have been balanced by cures or deaths of prevalent cases. If a large number of **healthy individuals emigrate** from the population, then the number of **cases** (numerator) would **remain the same**, but the **population size** would **decrease** (denominator). Therefore, estimates of disease **prevalence would increase**.

Educational objective:
Prevalence is the actual number of existing cases (old and new) of disease, either at a particular point in time (point prevalence), or during a period of time (period prevalence). Estimates of disease prevalence in a population are affected by population dynamics.

Biostatistics	Biostatistics & Epidemiology	Risk, rate, prevalence and incidence
Subject	System	Topic

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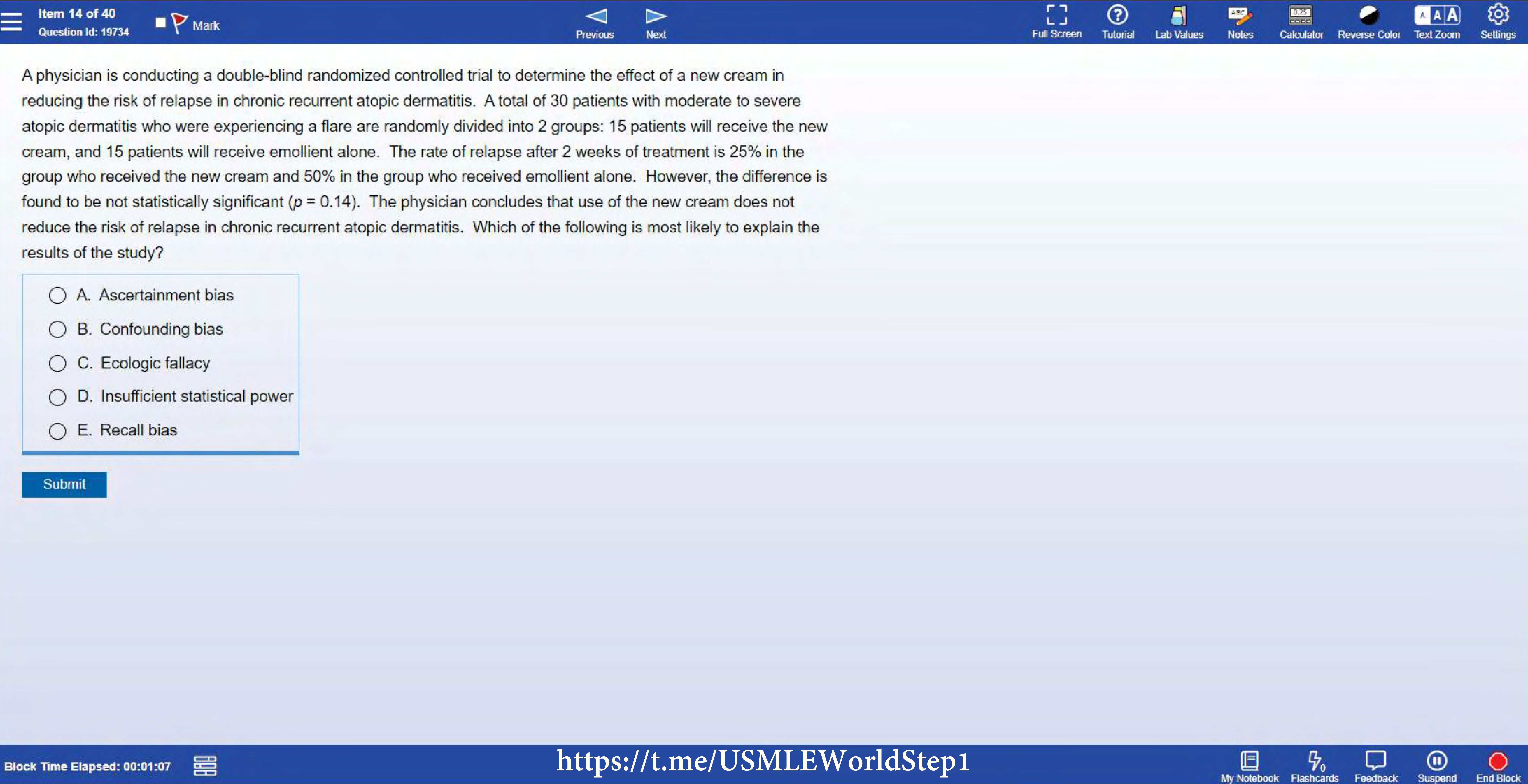
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Question Id: 19734

A physician is conducting a double-blind randomized controlled trial to determine the effect of a new cream in reducing the risk of relapse in chronic recurrent atopic dermatitis. A total of 30 patients with moderate to severe atopic dermatitis who were experiencing a flare are randomly divided into 2 groups: 15 patients will receive the new cream, and 15 patients will receive emollient alone. The rate of relapse after 2 weeks of treatment is 25% in the group who received the new cream and 50% in the group who received emollient alone. However, the difference is found to be not statistically significant ($p = 0.14$). The physician concludes that use of the new cream does not reduce the risk of relapse in chronic recurrent atopic dermatitis. Which of the following is most likely to explain the results of the study?

- ○ A. Ascertainment bias
- ○ B. Confounding bias
- ○ C. Ecologic fallacy
- ○ D. Insufficient statistical power
- ○ E. Recall bias

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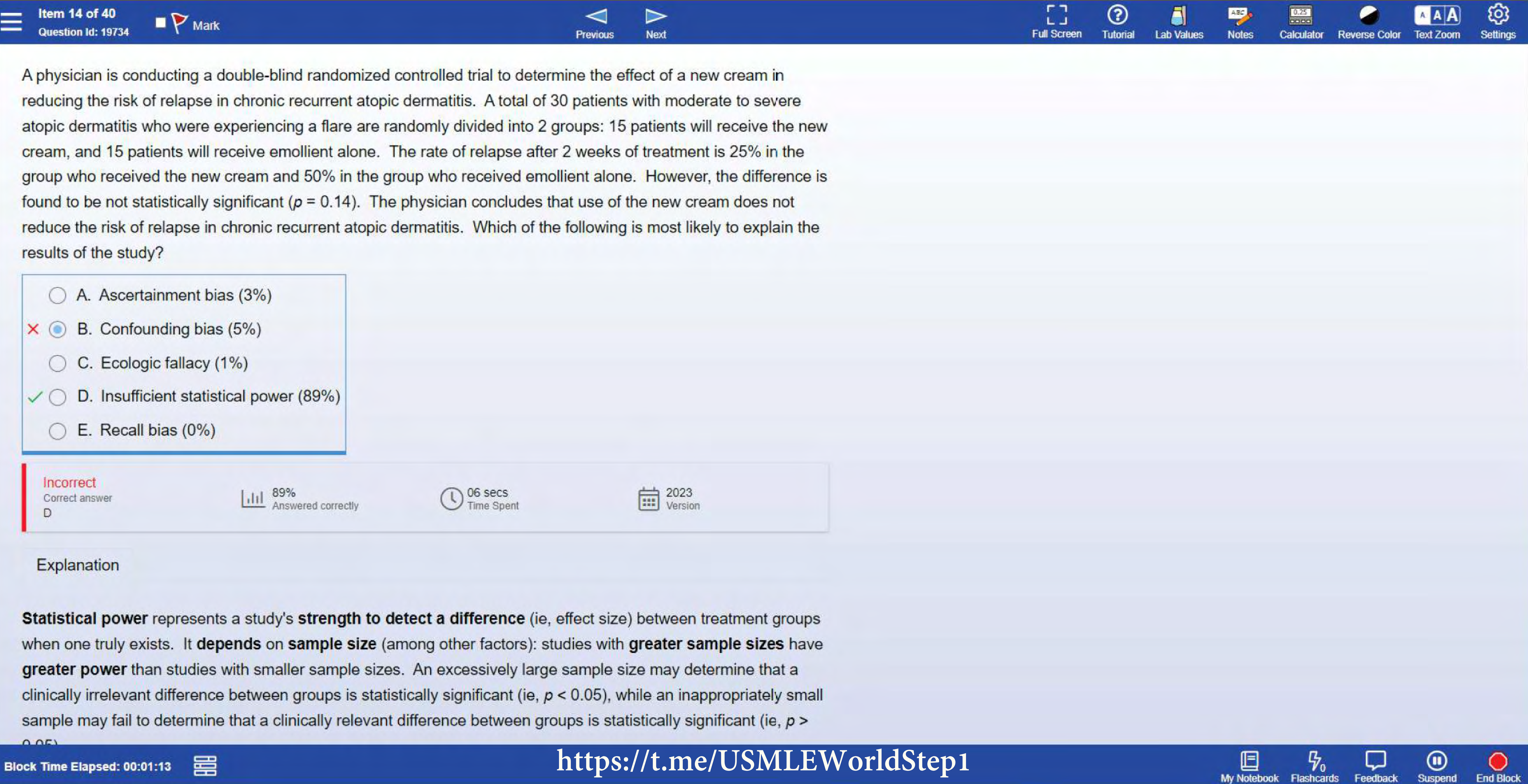
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○ A. Ascertainment bias (3%)
✗ ● B. Confounding bias (5%)
○ C. Ecologic fallacy (1%)
✓ ○ D. Insufficient statistical power (89%)
○ E. Recall bias (0%)

Incorrect
Correct answer
D

89%
Answered correctly

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Time Spent

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Explanation

Statistical power represents a study's **strength to detect a difference** (ie, effect size) between treatment groups when one truly exists. It **depends** on **sample size** (among other factors): studies with **greater sample sizes** have **greater power** than studies with smaller sample sizes. An excessively large sample size may determine that a clinically irrelevant difference between groups is statistically significant (ie, $p < 0.05$), while an inappropriately small sample may fail to determine that a clinically relevant difference between groups is statistically significant (ie, $p > 0.05$)

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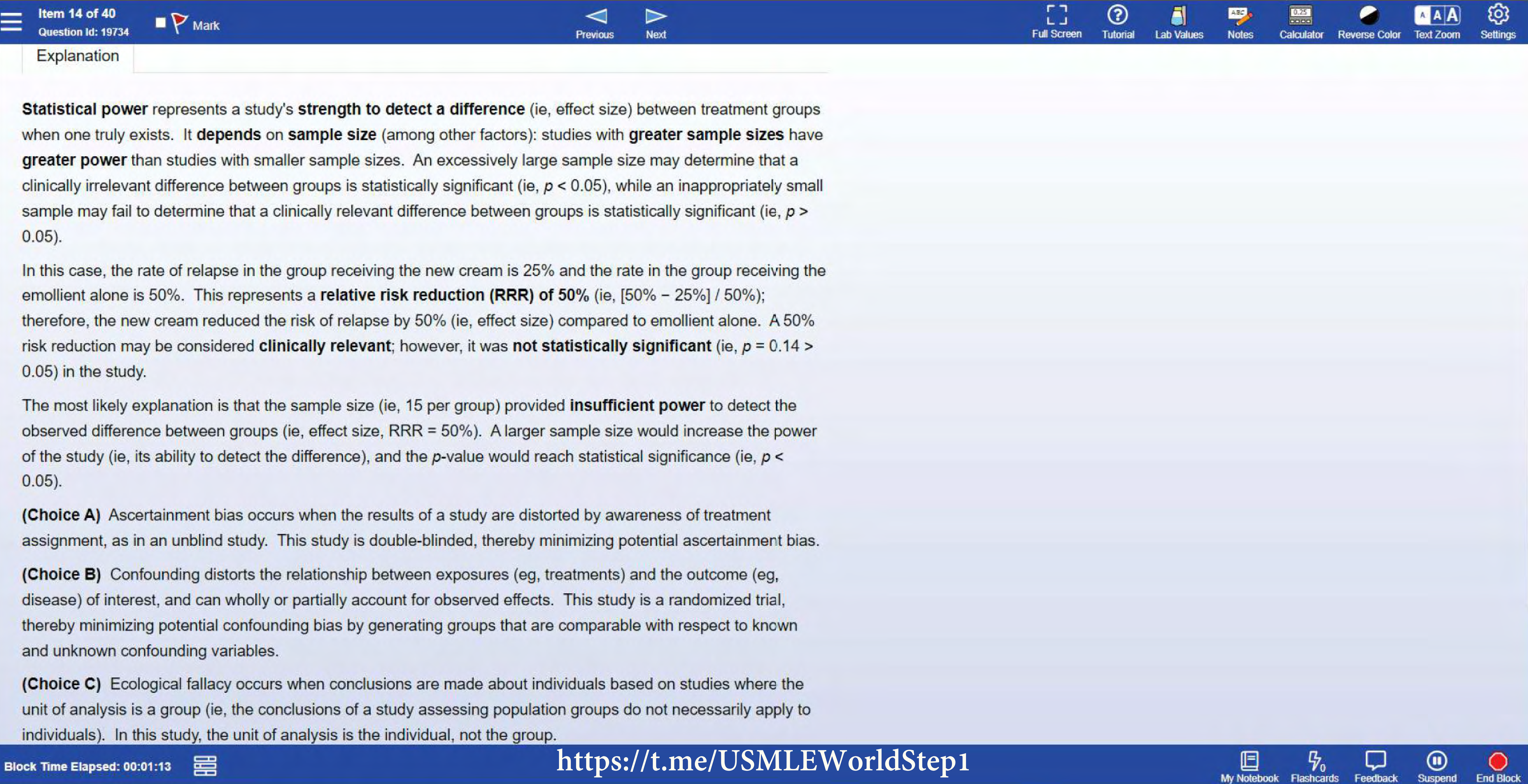

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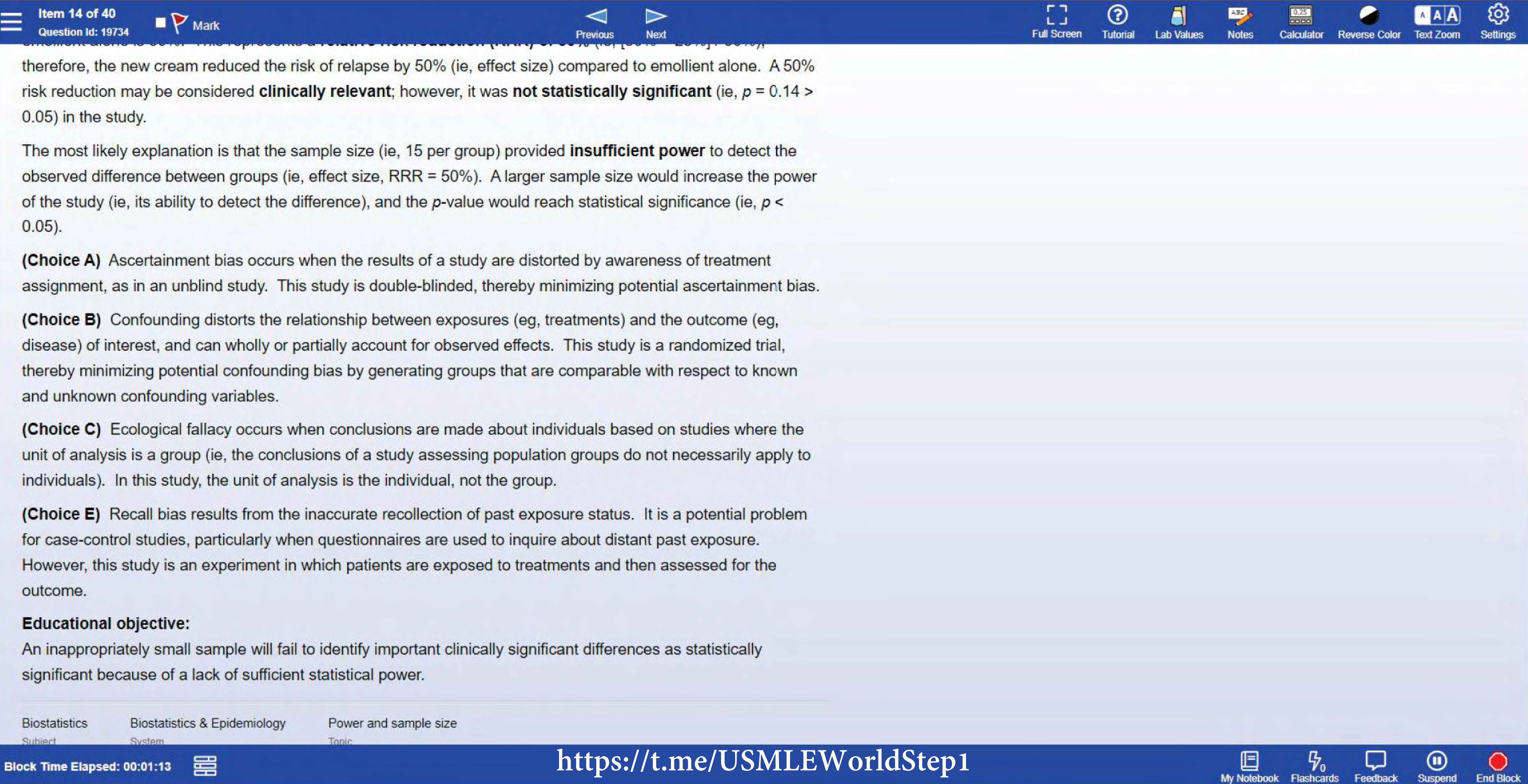
In this case, the rate of relapse in the group receiving the new cream is 25% and the rate in the group receiving the emollient alone is 50%. This represents a **relative risk reduction (RRR) of 50%** (ie, [50% − 25%] / 50%); therefore, the new cream reduced the risk of relapse by 50% (ie, effect size) compared to emollient alone. A 50% risk reduction may be considered **clinically relevant**; however, it was **not statistically significant** (ie, $p = 0.14 > 0.05$) in the study.

The most likely explanation is that the sample size (ie, 15 per group) provided **insufficient power** to detect the observed difference between groups (ie, effect size, RRR = 50%). A larger sample size would increase the power of the study (ie, its ability to detect the difference), and the *p*-value would reach statistical significance (ie, $p < 0.05$).

(Choice A) Ascertainment bias occurs when the results of a study are distorted by awareness of treatment assignment, as in an unblind study. This study is double-blinded, thereby minimizing potential ascertainment bias.

(Choice B) Confounding distorts the relationship between exposures (eg, treatments) and the outcome (eg, disease) of interest, and can wholly or partially account for observed effects. This study is a randomized trial, thereby minimizing potential confounding bias by generating groups that are comparable with respect to known and unknown confounding variables.

(Choice C) Ecological fallacy occurs when conclusions are made about individuals based on studies where the unit of analysis is a group (ie, the conclusions of a study assessing population groups do not necessarily apply to individuals). In this study, the unit of analysis is the individual, not the group.



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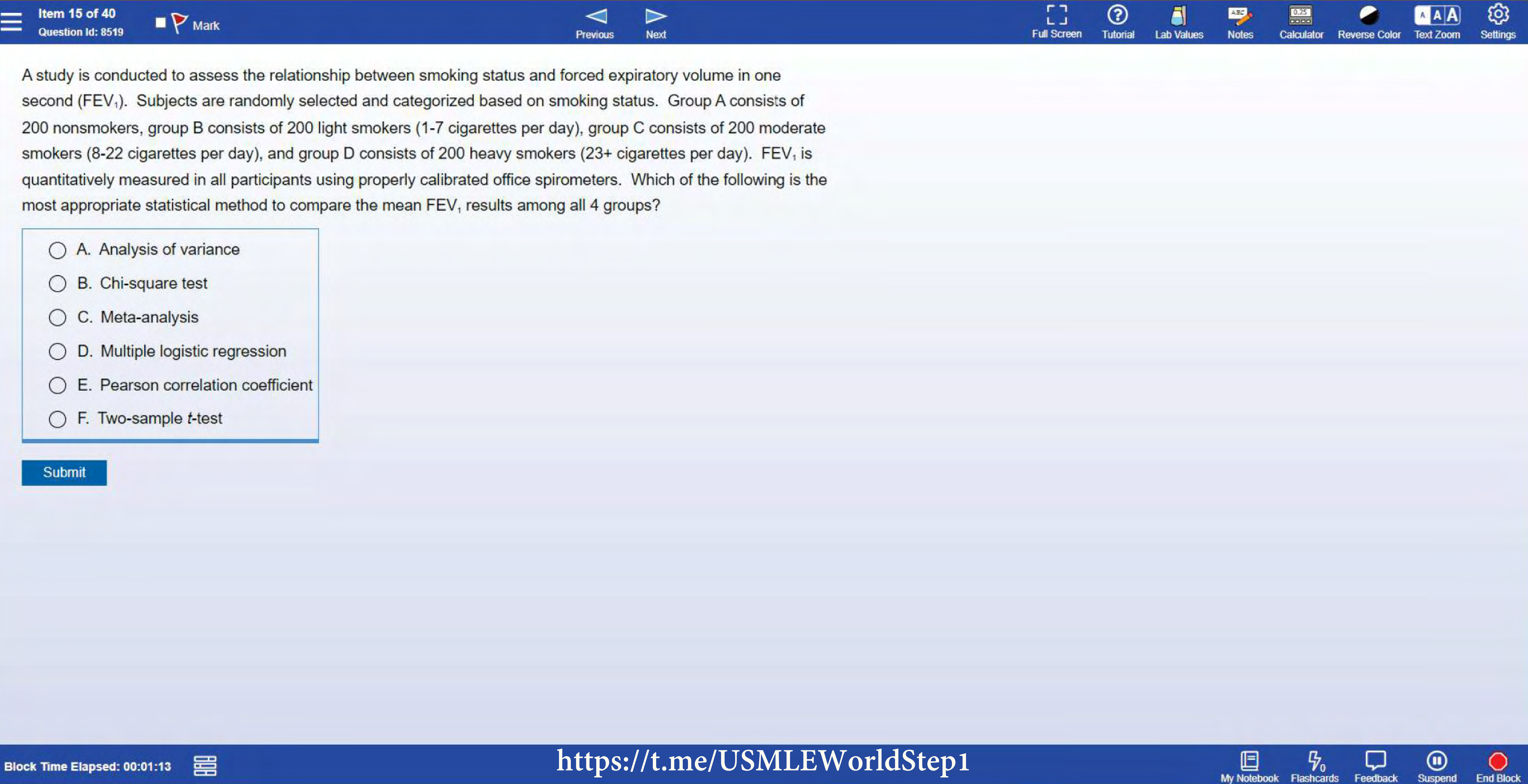
(Choice E) Recall bias results from the inaccurate recollection of past exposure status. It is a potential problem for case-control studies, particularly when questionnaires are used to inquire about distant past exposure. However, this study is an experiment in which patients are exposed to treatments and then assessed for the outcome.

Educational objective:

An inappropriately small sample will fail to identify important clinically significant differences as statistically significant because of a lack of sufficient statistical power.

Biostatistics	Biostatistics & Epidemiology	Power and sample size
Subject	System	Topic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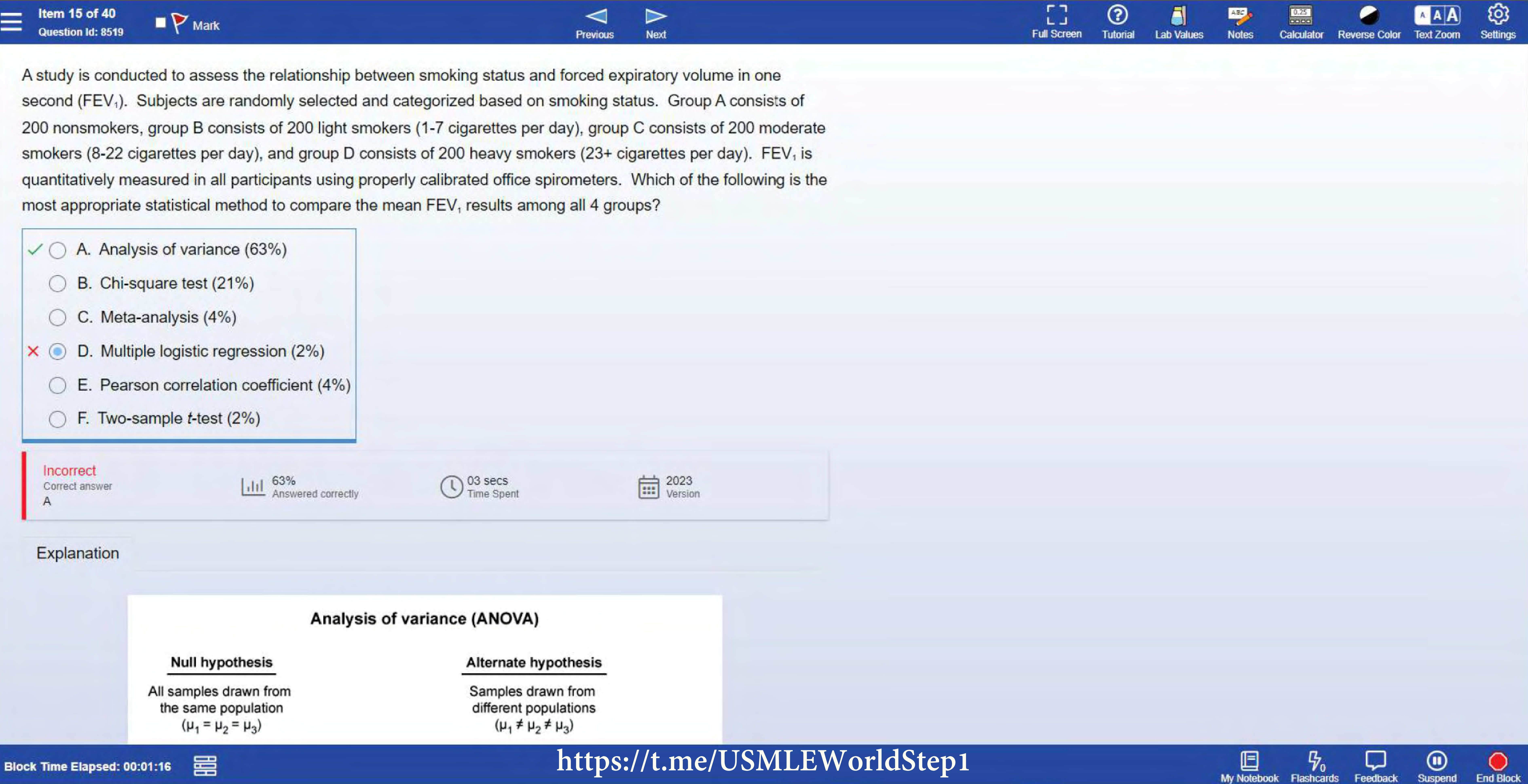
A study is conducted to assess the relationship between smoking status and forced expiratory volume in one second (FEV$_1$). Subjects are randomly selected and categorized based on smoking status. Group A consists of 200 nonsmokers, group B consists of 200 light smokers (1-7 cigarettes per day), group C consists of 200 moderate smokers (8-22 cigarettes per day), and group D consists of 200 heavy smokers (23+ cigarettes per day). FEV$_1$ is quantitatively measured in all participants using properly calibrated office spirometers. Which of the following is the most appropriate statistical method to compare the mean FEV$_1$ results among all 4 groups?

○ A. Analysis of variance
○ B. Chi-square test
○ C. Meta-analysis
○ D. Multiple logistic regression
○ E. Pearson correlation coefficient
○ F. Two-sample *t*-test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A study is conducted to assess the relationship between smoking status and forced expiratory volume in one second (FEV_1). Subjects are randomly selected and categorized based on smoking status. Group A consists of 200 nonsmokers, group B consists of 200 light smokers (1-7 cigarettes per day), group C consists of 200 moderate smokers (8-22 cigarettes per day), and group D consists of 200 heavy smokers (23+ cigarettes per day). FEV_1 is quantitatively measured in all participants using properly calibrated office spirometers. Which of the following is the most appropriate statistical method to compare the mean FEV_1 results among all 4 groups?

✓ ○ A. Analysis of variance (63%)
○ B. Chi-square test (21%)
○ C. Meta-analysis (4%)
✗ ● D. Multiple logistic regression (2%)
○ E. Pearson correlation coefficient (4%)
○ F. Two-sample *t*-test (2%)

Incorrect
Correct answer
A

63%
Answered correctly

03 secs
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Explanation

Analysis of variance (ANOVA)

Null hypothesis	Alternate hypothesis
All samples drawn from the same population ($\mu_1 = \mu_2 = \mu_3$)	Samples drawn from different populations ($\mu_1 \neq \mu_2 \neq \mu_3$)

Explanation

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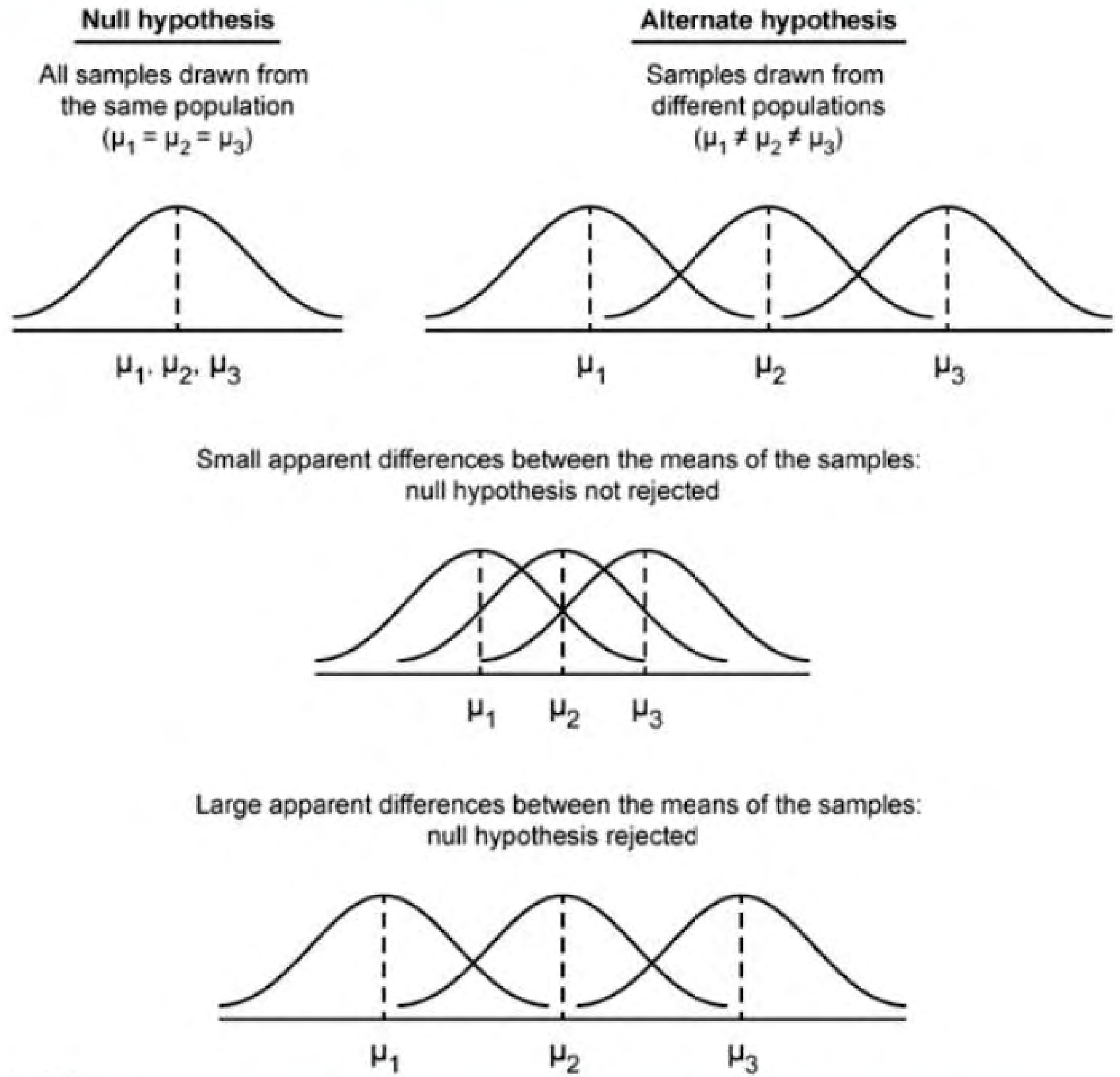
Analysis of variance (ANOVA)



Small apparent differences between the means of the samples: null hypothesis not rejected

Large apparent differences between the means of the samples: null hypothesis rejected

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Analysis of variance (ANOVA) is used to determine whether there are any significant **differences between the**

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Analysis of variance (ANOVA) is used to determine whether there are any significant **differences between the means** of **several independent groups**.

ANOVA compares the means between the groups relative to the variability within groups (F-test) and determines whether any of those means are significantly different from one another. Specifically, it tests the **null hypothesis** that all groups are simply random samples of the same population (ie, the **means are the same**). The null hypothesis is rejected when there are at least 2 group means that are significantly different from one another.

ANOVA can be used to compare ≥2 groups but is generally used to compare **≥3 groups** (because other equivalent methods exist to compare 2 groups). For example, the 2 independent samples *t*-test is a special case of the F-test in ANOVA. The assumptions for both tests and their resulting *p*-values are the same.

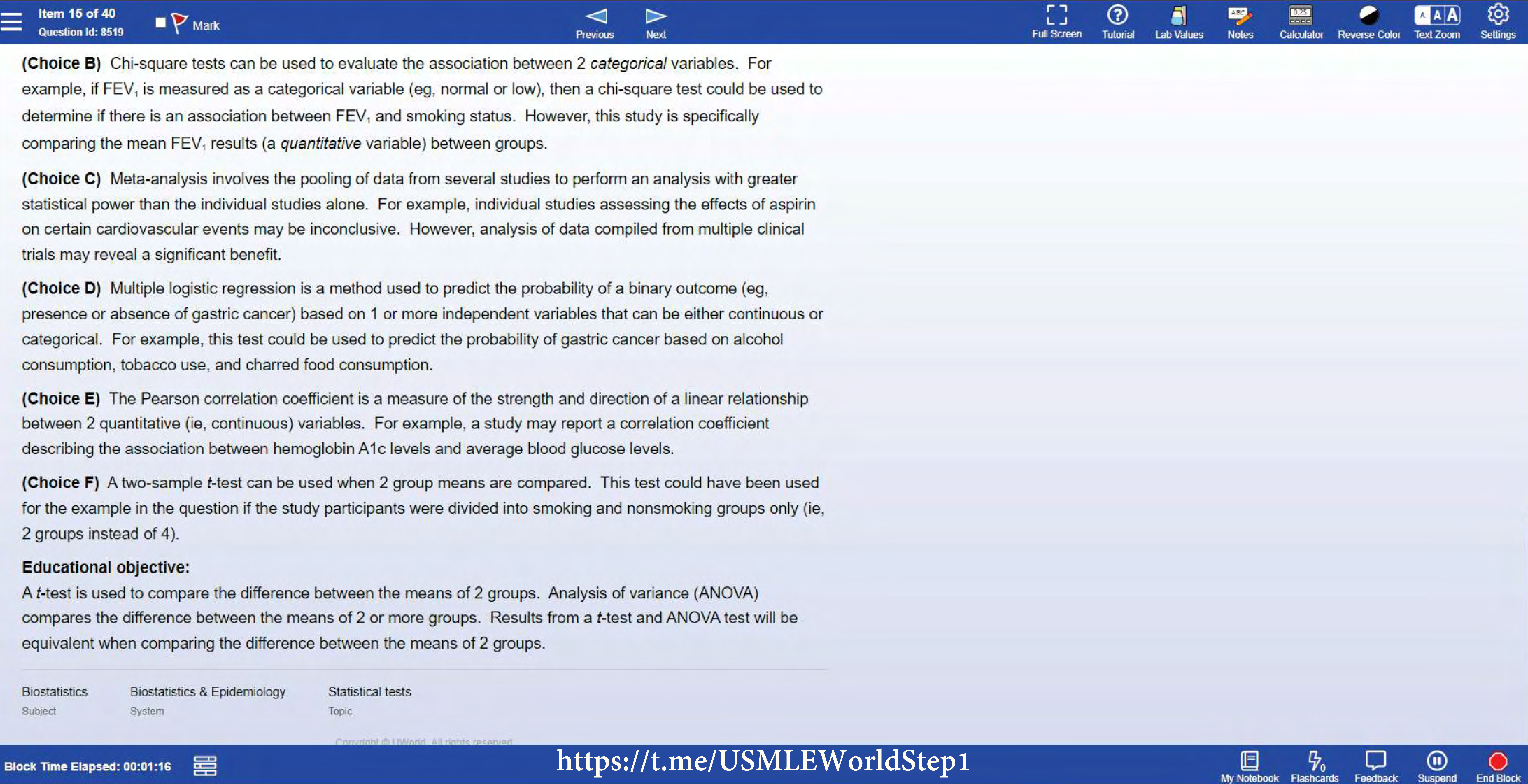
(Choice B) Chi-square tests can be used to evaluate the association between 2 *categorical* variables. For example, if FEV_1 is measured as a categorical variable (eg, normal or low), then a chi-square test could be used to determine if there is an association between FEV_1 and smoking status. However, this study is specifically comparing the mean FEV_1 results (a *quantitative* variable) between groups.

(Choice C) Meta-analysis involves the pooling of data from several studies to perform an analysis with greater statistical power than the individual studies alone. For example, individual studies assessing the effects of aspirin on certain cardiovascular events may be inconclusive. However, analysis of data compiled from multiple clinical trials may reveal a significant benefit.

(Choice D) Multiple logistic regression is a method used to predict the probability of a binary outcome (eg, presence or absence of gastric cancer) based on 1 or more independent variables that can be either continuous or categorical. For example, this test could be used to predict the probability of gastric cancer based on alcohol consumption, tobacco use, and charred food consumption.

(Choice E) The Pearson correlation coefficient is a measure of the strength and direction of a linear relationship between 2 quantitative (ie, continuous) variables. For example, a study may report a correlation coefficient describing the association between hemoglobin A1c levels and average blood glucose levels.

(Choice F) A two-sample *t*-test can be used when 2 group means are compared. This test could have been used



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(Choice E) The Pearson correlation coefficient is a measure of the strength and direction of a linear relationship between 2 quantitative (ie, continuous) variables. For example, a study may report a correlation coefficient describing the association between hemoglobin A1c levels and average blood glucose levels.

(Choice F) A two-sample *t*-test can be used when 2 group means are compared. This test could have been used for the example in the question if the study participants were divided into smoking and nonsmoking groups only (ie, 2 groups instead of 4).

Educational objective:

A *t*-test is used to compare the difference between the means of 2 groups. Analysis of variance (ANOVA) compares the difference between the means of 2 or more groups. Results from a *t*-test and ANOVA test will be equivalent when comparing the difference between the means of 2 groups.

Biostatistics	Biostatistics & Epidemiology	Statistical tests
Subject	System	Topic

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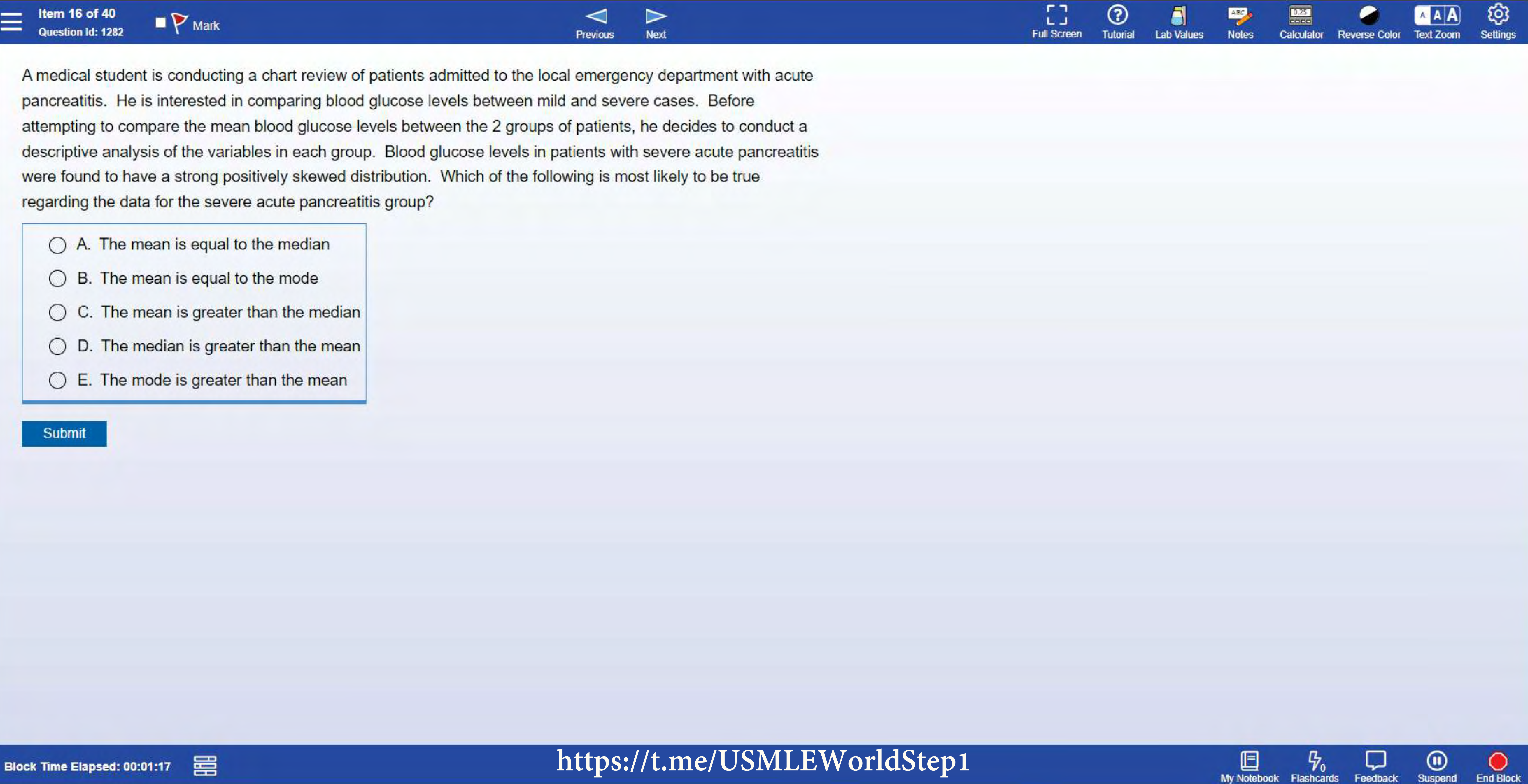
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A medical student is conducting a chart review of patients admitted to the local emergency department with acute pancreatitis. He is interested in comparing blood glucose levels between mild and severe cases. Before attempting to compare the mean blood glucose levels between the 2 groups of patients, he decides to conduct a descriptive analysis of the variables in each group. Blood glucose levels in patients with severe acute pancreatitis were found to have a strong positively skewed distribution. Which of the following is most likely to be true regarding the data for the severe acute pancreatitis group?

- ○ A. The mean is equal to the median
- ○ B. The mean is equal to the mode
- ○ C. The mean is greater than the median
- ○ D. The median is greater than the mean
- ○ E. The mode is greater than the mean

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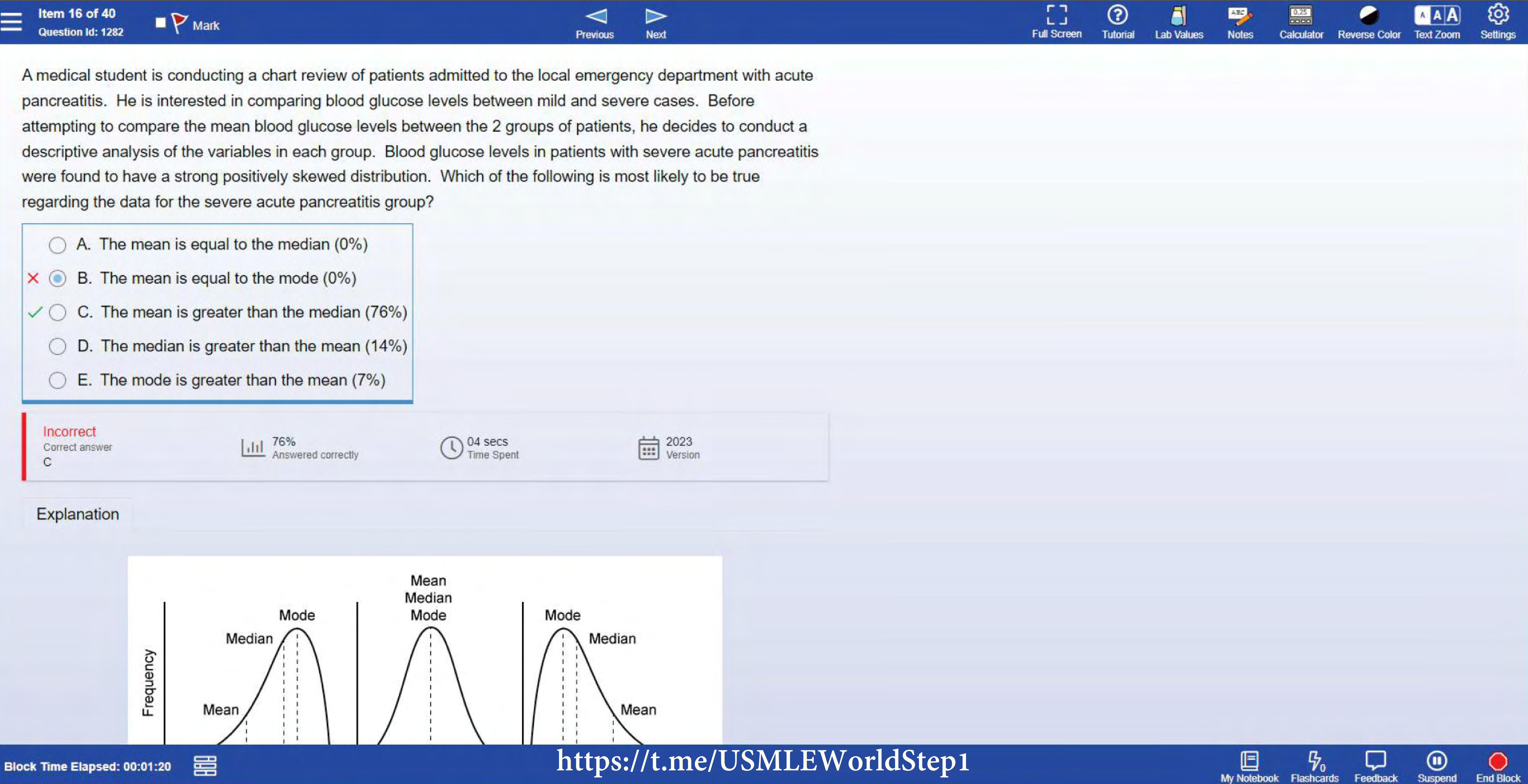
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- ○ A. The mean is equal to the median (0%)
- ✗ ● B. The mean is equal to the mode (0%)
- ✓ ○ C. The mean is greater than the median (76%)
- ○ D. The median is greater than the mean (14%)
- ○ E. The mode is greater than the mean (7%)

Incorrect
Correct answer
C

76%
Answered correctly

04 secs
Time Spent

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Version

Explanation

Frequency
Mean
Median
Mode
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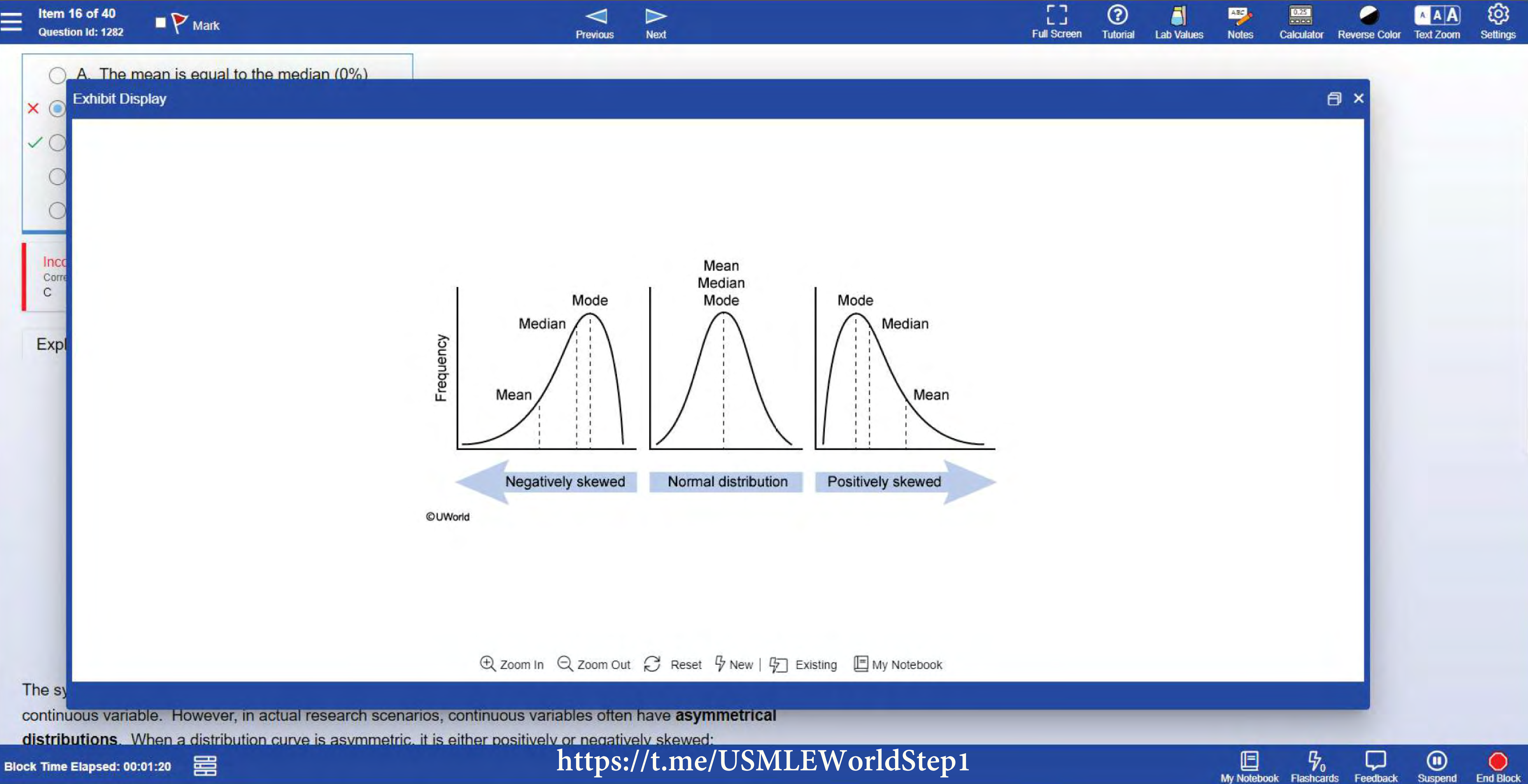
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Normal distribution
Positively skewed
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○ A. The mean is equal to the median (0%)

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C

Expl

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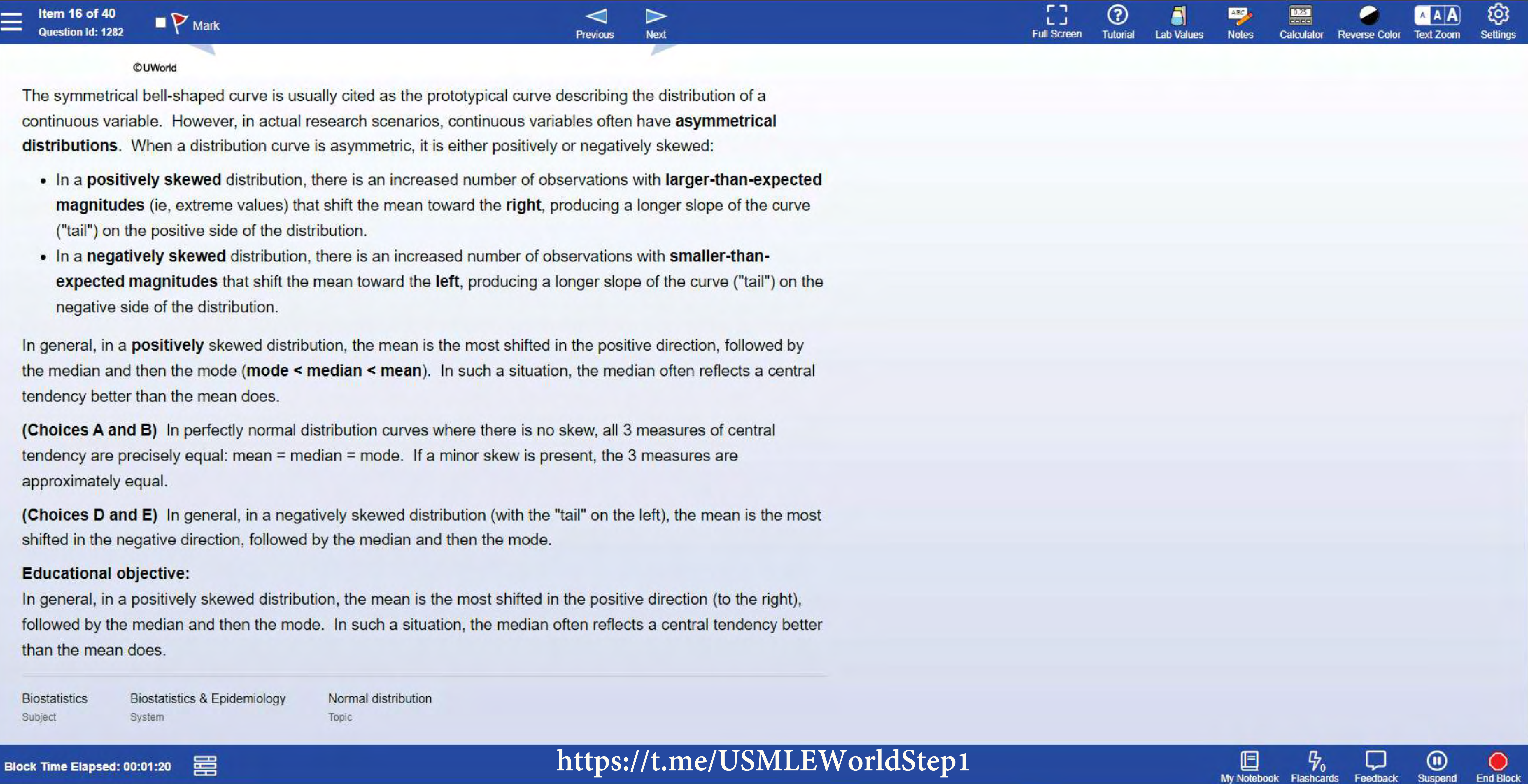
continuous variable. However, in actual research scenarios, continuous variables often have **asymmetrical distributions**. When a distribution curve is asymmetric, it is either positively or negatively skewed: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The symmetrical bell-shaped curve is usually cited as the prototypical curve describing the distribution of a continuous variable. However, in actual research scenarios, continuous variables often have **asymmetrical distributions**. When a distribution curve is asymmetric, it is either positively or negatively skewed:

- In a **positively skewed** distribution, there is an increased number of observations with **larger-than-expected magnitudes** (ie, extreme values) that shift the mean toward the **right**, producing a longer slope of the curve ("tail") on the positive side of the distribution.
- In a **negatively skewed** distribution, there is an increased number of observations with **smaller-than-expected magnitudes** that shift the mean toward the **left**, producing a longer slope of the curve ("tail") on the negative side of the distribution.

In general, in a **positively** skewed distribution, the mean is the most shifted in the positive direction, followed by the median and then the mode (**mode < median < mean**). In such a situation, the median often reflects a central tendency better than the mean does.

(Choices A and B) In perfectly normal distribution curves where there is no skew, all 3 measures of central tendency are precisely equal: mean = median = mode. If a minor skew is present, the 3 measures are approximately equal.

(Choices D and E) In general, in a negatively skewed distribution (with the "tail" on the left), the mean is the most shifted in the negative direction, followed by the median and then the mode.

Educational objective:

In general, in a positively skewed distribution, the mean is the most shifted in the positive direction (to the right), followed by the median and then the mode. In such a situation, the median often reflects a central tendency better than the mean does.

Biostatistics	Biostatistics & Epidemiology	Normal distribution
Subject	System	Topic

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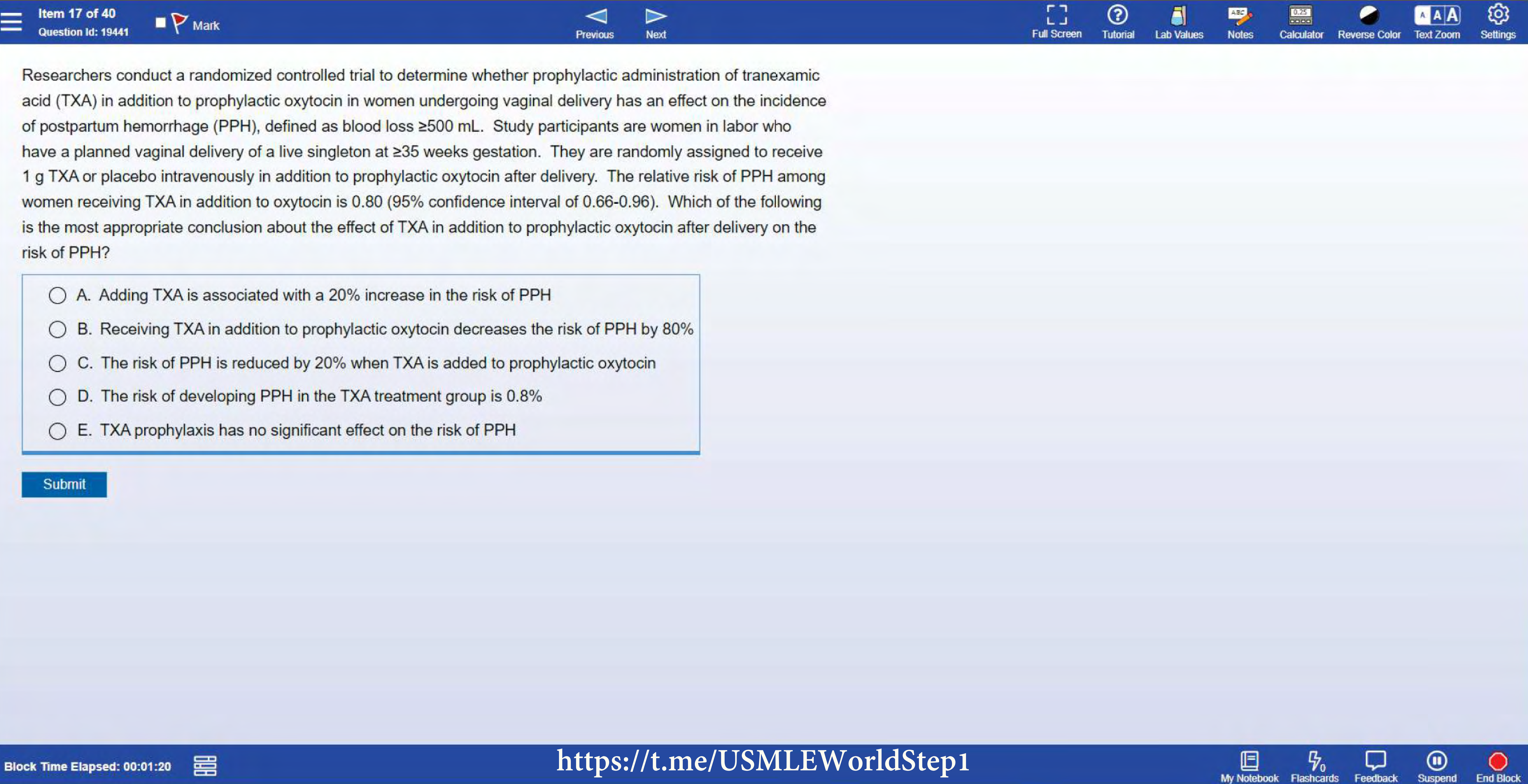
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Question Id: 19441

Researchers conduct a randomized controlled trial to determine whether prophylactic administration of tranexamic acid (TXA) in addition to prophylactic oxytocin in women undergoing vaginal delivery has an effect on the incidence of postpartum hemorrhage (PPH), defined as blood loss ≥500 mL. Study participants are women in labor who have a planned vaginal delivery of a live singleton at ≥35 weeks gestation. They are randomly assigned to receive 1 g TXA or placebo intravenously in addition to prophylactic oxytocin after delivery. The relative risk of PPH among women receiving TXA in addition to oxytocin is 0.80 (95% confidence interval of 0.66-0.96). Which of the following is the most appropriate conclusion about the effect of TXA in addition to prophylactic oxytocin after delivery on the risk of PPH?

○ A. Adding TXA is associated with a 20% increase in the risk of PPH

○ B. Receiving TXA in addition to prophylactic oxytocin decreases the risk of PPH by 80%

○ C. The risk of PPH is reduced by 20% when TXA is added to prophylactic oxytocin

○ D. The risk of developing PPH in the TXA treatment group is 0.8%

○ E. TXA prophylaxis has no significant effect on the risk of PPH

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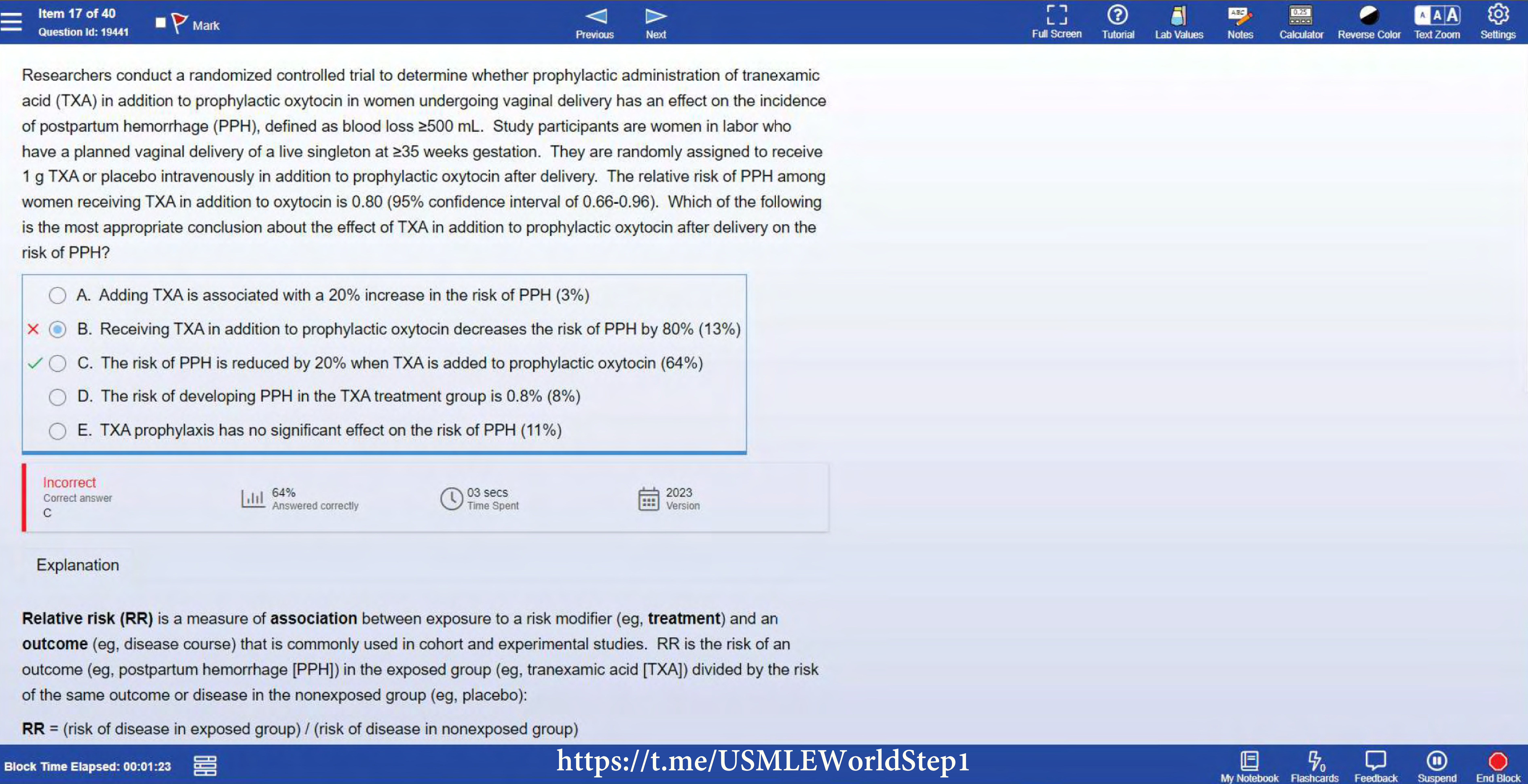
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○ A. Adding TXA is associated with a 20% increase in the risk of PPH (3%)

✗ ● B. Receiving TXA in addition to prophylactic oxytocin decreases the risk of PPH by 80% (13%)

✓ ○ C. The risk of PPH is reduced by 20% when TXA is added to prophylactic oxytocin (64%)

○ D. The risk of developing PPH in the TXA treatment group is 0.8% (8%)

○ E. TXA prophylaxis has no significant effect on the risk of PPH (11%)

Incorrect
Correct answer
C

64%
Answered correctly

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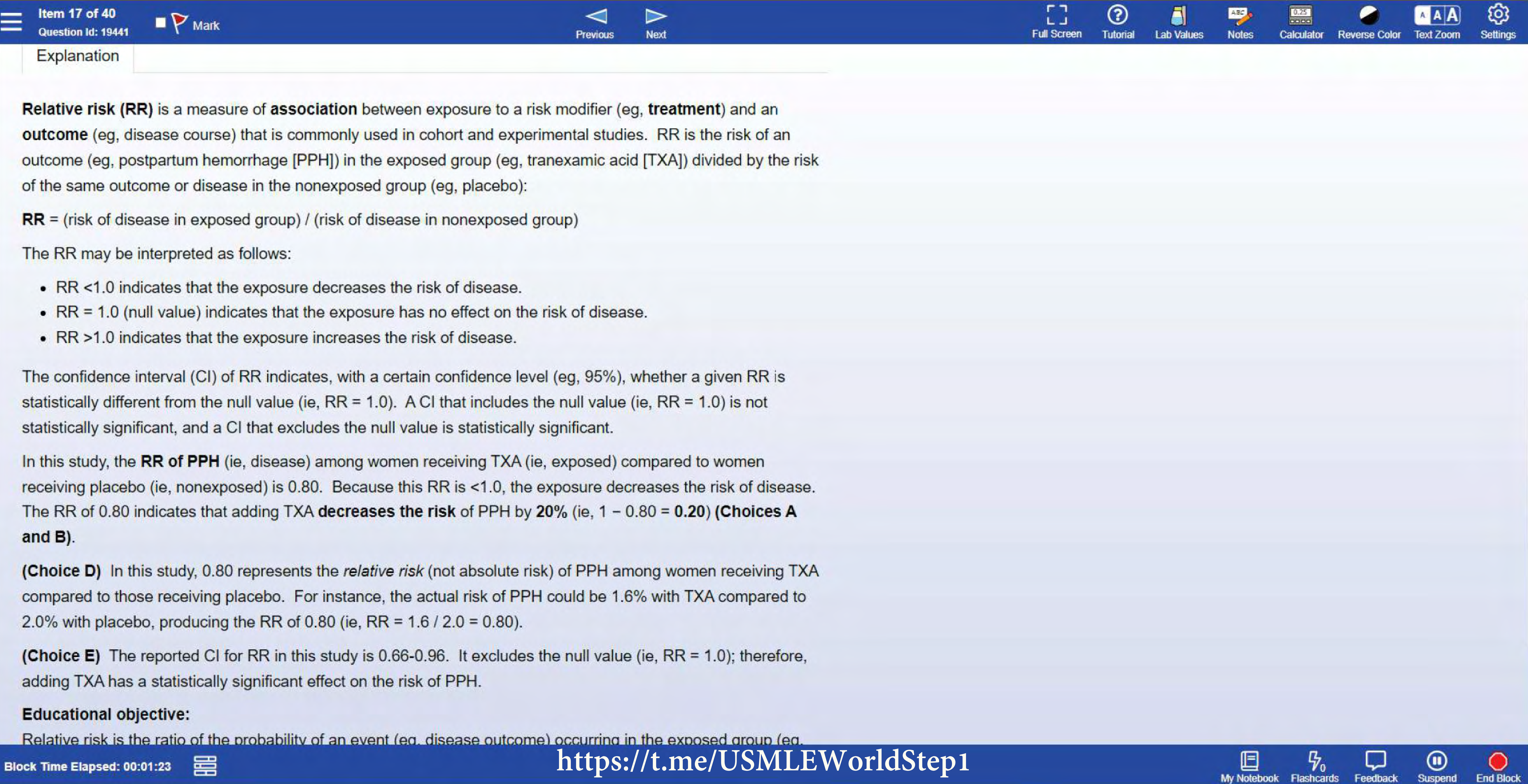
Explanation

Relative risk (RR) is a measure of **association** between exposure to a risk modifier (eg, **treatment**) and an **outcome** (eg, disease course) that is commonly used in cohort and experimental studies. RR is the risk of an outcome (eg, postpartum hemorrhage [PPH]) in the exposed group (eg, tranexamic acid [TXA]) divided by the risk of the same outcome or disease in the nonexposed group (eg, placebo):

RR = (risk of disease in exposed group) / (risk of disease in nonexposed group)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Explanation
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RR = (risk of disease in exposed group) / (risk of disease in nonexposed group)

The RR may be interpreted as follows:

- RR <1.0 indicates that the exposure decreases the risk of disease.
- RR = 1.0 (null value) indicates that the exposure has no effect on the risk of disease.
- RR >1.0 indicates that the exposure increases the risk of disease.

The confidence interval (CI) of RR indicates, with a certain confidence level (eg, 95%), whether a given RR is statistically different from the null value (ie, RR = 1.0). A CI that includes the null value (ie, RR = 1.0) is not statistically significant, and a CI that excludes the null value is statistically significant.

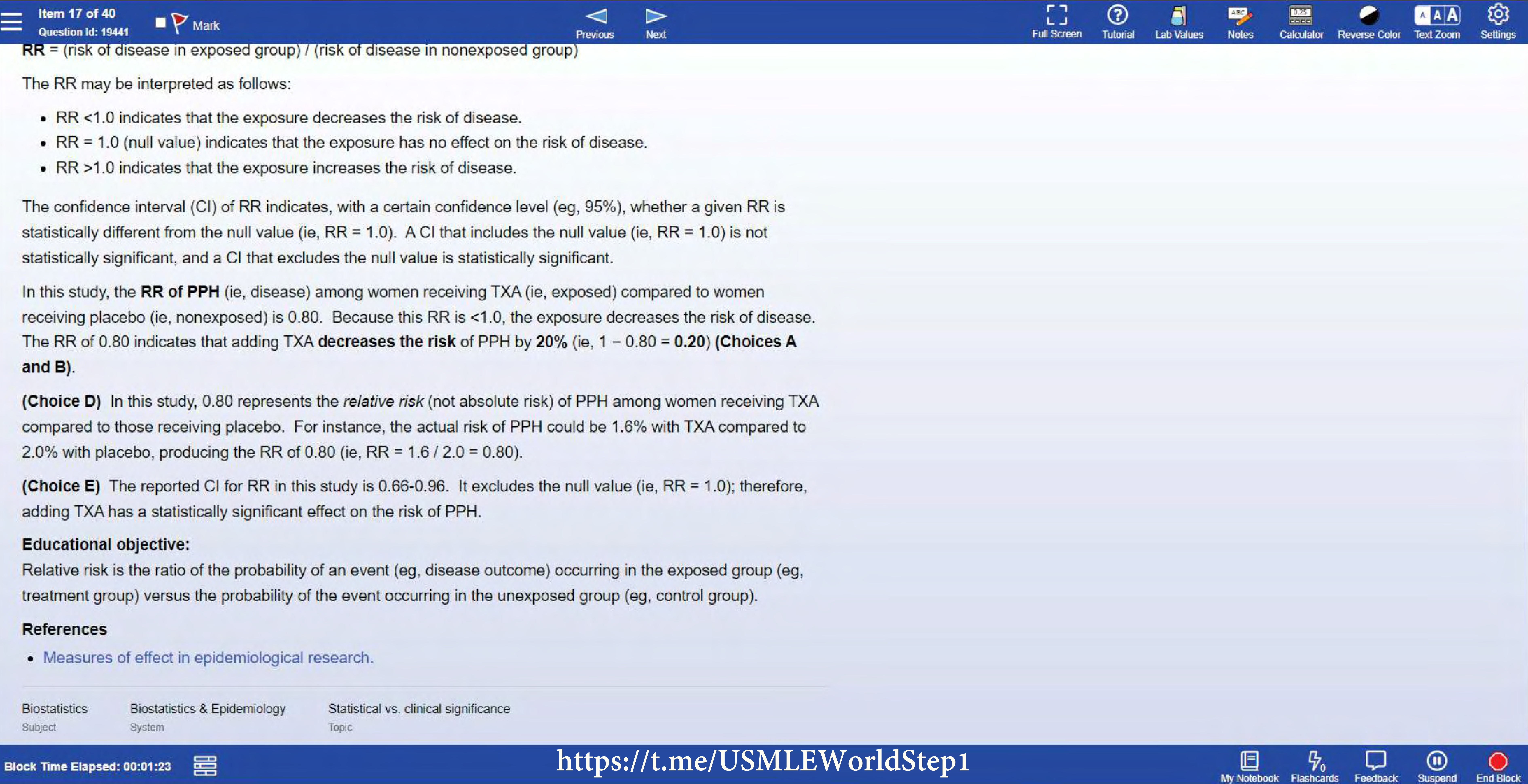
In this study, the **RR of PPH** (ie, disease) among women receiving TXA (ie, exposed) compared to women receiving placebo (ie, nonexposed) is 0.80. Because this RR is <1.0, the exposure decreases the risk of disease. The RR of 0.80 indicates that adding TXA **decreases the risk** of PPH by **20%** (ie, 1 − 0.80 = **0.20**) **(Choices A and B)**.

(Choice D) In this study, 0.80 represents the *relative risk* (not absolute risk) of PPH among women receiving TXA compared to those receiving placebo. For instance, the actual risk of PPH could be 1.6% with TXA compared to 2.0% with placebo, producing the RR of 0.80 (ie, RR = 1.6 / 2.0 = 0.80).

(Choice E) The reported CI for RR in this study is 0.66-0.96. It excludes the null value (ie, RR = 1.0); therefore, adding TXA has a statistically significant effect on the risk of PPH.

Educational objective:

Relative risk is the ratio of the probability of an event (eg, disease outcome) occurring in the exposed group (eg,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RR = (risk of disease in exposed group) / (risk of disease in nonexposed group)

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(Choice D) In this study, 0.80 represents the *relative risk* (not absolute risk) of PPH among women receiving TXA compared to those receiving placebo. For instance, the actual risk of PPH could be 1.6% with TXA compared to 2.0% with placebo, producing the RR of 0.80 (ie, RR = 1.6 / 2.0 = 0.80).

(Choice E) The reported CI for RR in this study is 0.66-0.96. It excludes the null value (ie, RR = 1.0); therefore, adding TXA has a statistically significant effect on the risk of PPH.

Educational objective:

Relative risk is the ratio of the probability of an event (eg, disease outcome) occurring in the exposed group (eg, treatment group) versus the probability of the event occurring in the unexposed group (eg, control group).

References

- Measures of effect in epidemiological research.

Biostatistics	Biostatistics & Epidemiology	Statistical vs. clinical significance
Subject	System	Topic

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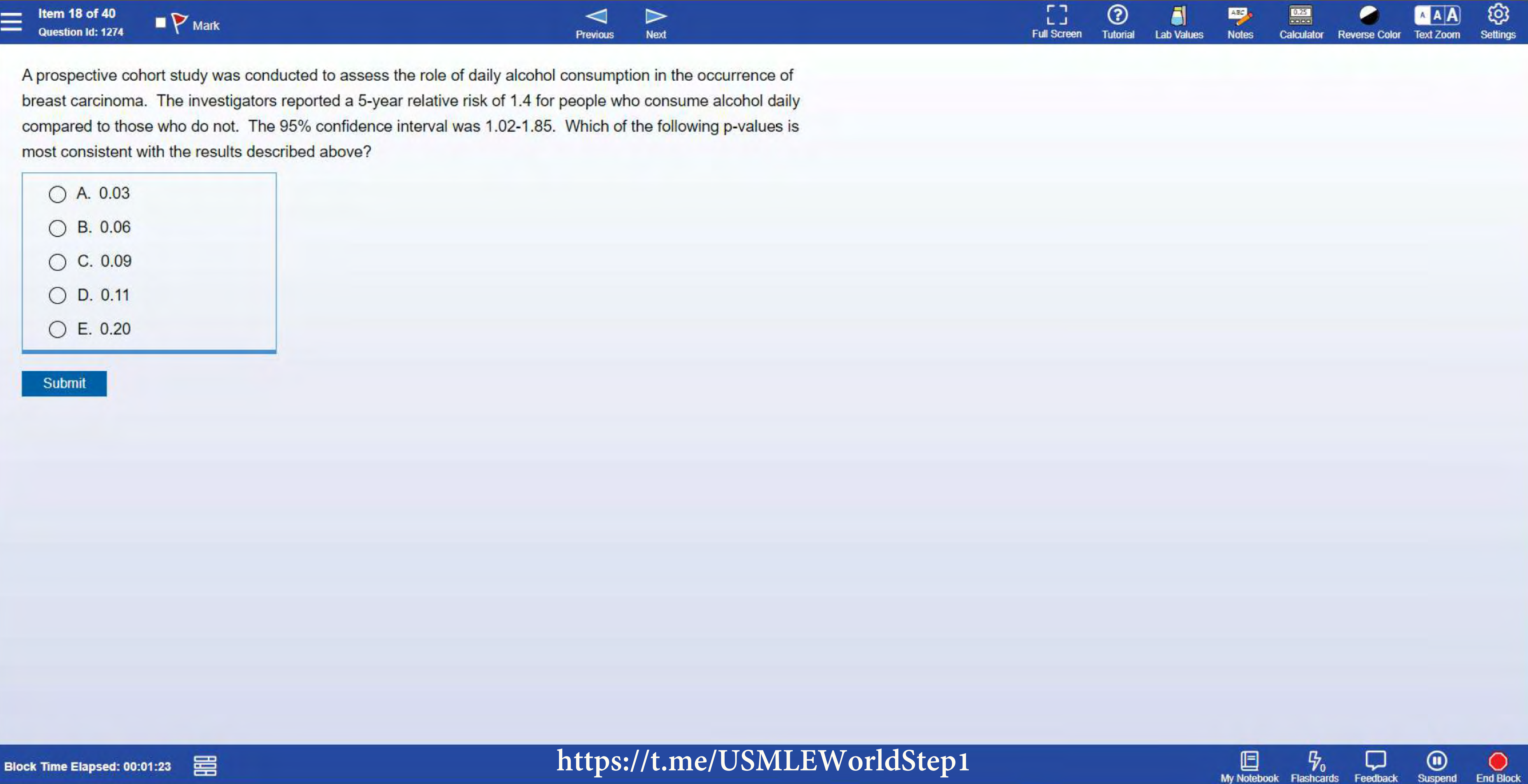
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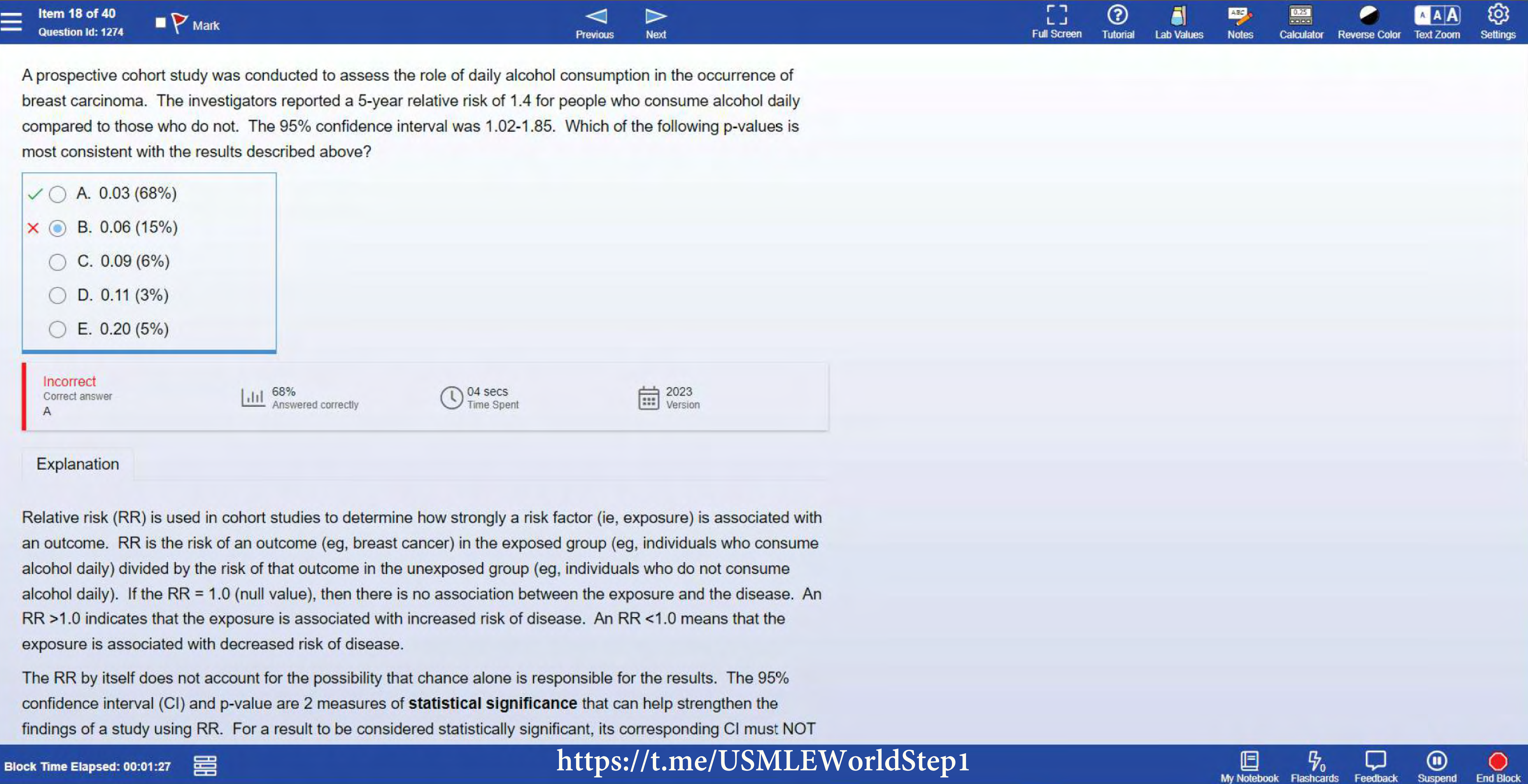
A prospective cohort study was conducted to assess the role of daily alcohol consumption in the occurrence of breast carcinoma. The investigators reported a 5-year relative risk of 1.4 for people who consume alcohol daily compared to those who do not. The 95% confidence interval was 1.02-1.85. Which of the following p-values is most consistent with the results described above?

- ○ A. 0.03
- ○ B. 0.06
- ○ C. 0.09
- ○ D. 0.11
- ○ E. 0.20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- ✓ ○ A. 0.03 (68%)
- ✗ ● B. 0.06 (15%)
- ○ C. 0.09 (6%)
- ○ D. 0.11 (3%)
- ○ E. 0.20 (5%)

Incorrect
Correct answer
A

68%
Answered correctly

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Time Spent

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Explanation

Relative risk (RR) is used in cohort studies to determine how strongly a risk factor (ie, exposure) is associated with an outcome. RR is the risk of an outcome (eg, breast cancer) in the exposed group (eg, individuals who consume alcohol daily) divided by the risk of that outcome in the unexposed group (eg, individuals who do not consume alcohol daily). If the RR = 1.0 (null value), then there is no association between the exposure and the disease. An RR >1.0 indicates that the exposure is associated with increased risk of disease. An RR <1.0 means that the exposure is associated with decreased risk of disease.

The RR by itself does not account for the possibility that chance alone is responsible for the results. The 95% confidence interval (CI) and p-value are 2 measures of **statistical significance** that can help strengthen the findings of a study using RR. For a result to be considered statistically significant, its corresponding CI must NOT

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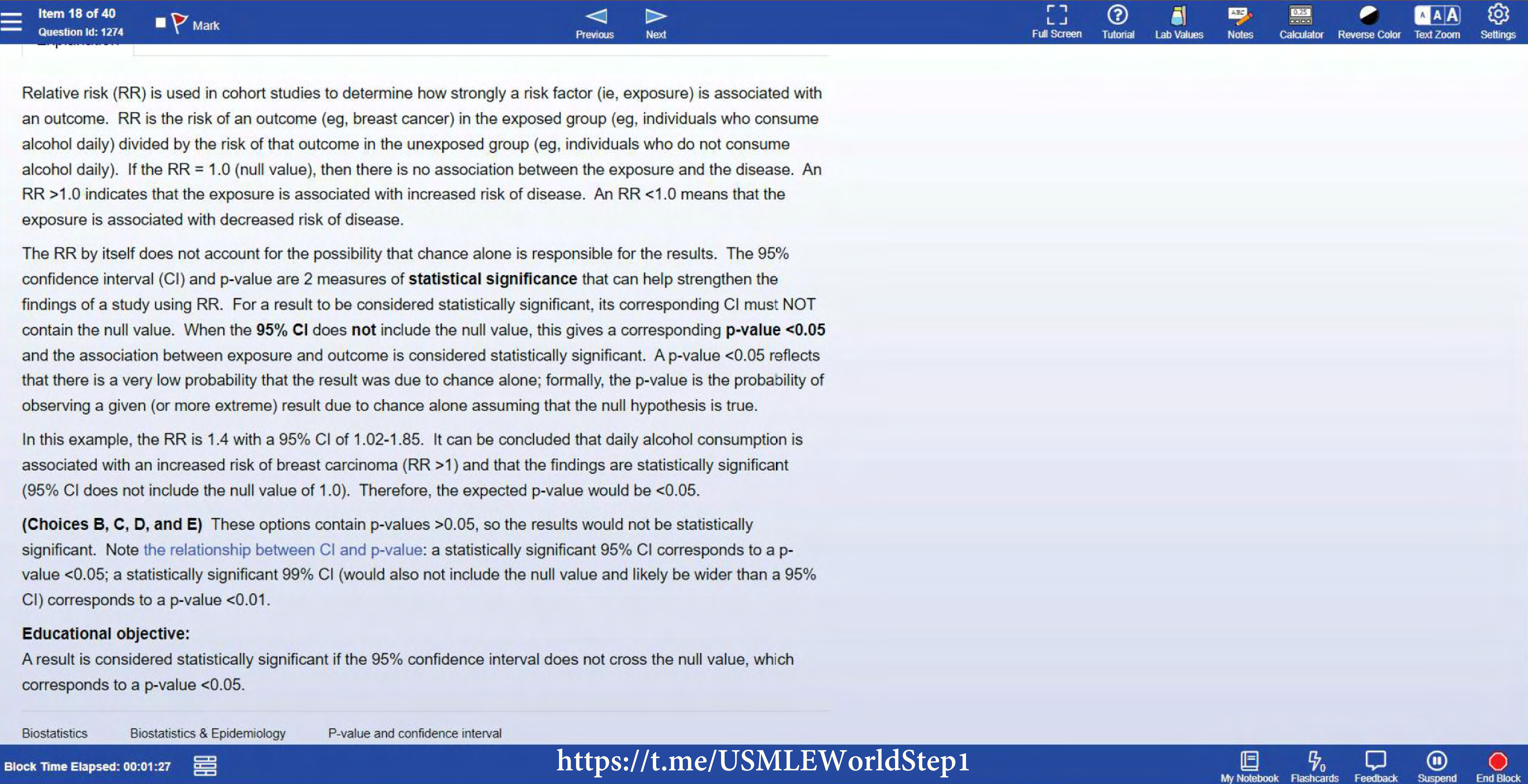


Relative risk (RR) is used in cohort studies to determine how strongly a risk factor (ie, exposure) is associated with an outcome. RR is the risk of an outcome (eg, breast cancer) in the exposed group (eg, individuals who consume alcohol daily) divided by the risk of that outcome in the unexposed group (eg, individuals who do not consume alcohol daily). If the RR = 1.0 (null value), then there is no association between the exposure and the disease. An RR >1.0 indicates that the exposure is associated with increased risk of disease. An RR <1.0 means that the exposure is associated with decreased risk of disease.

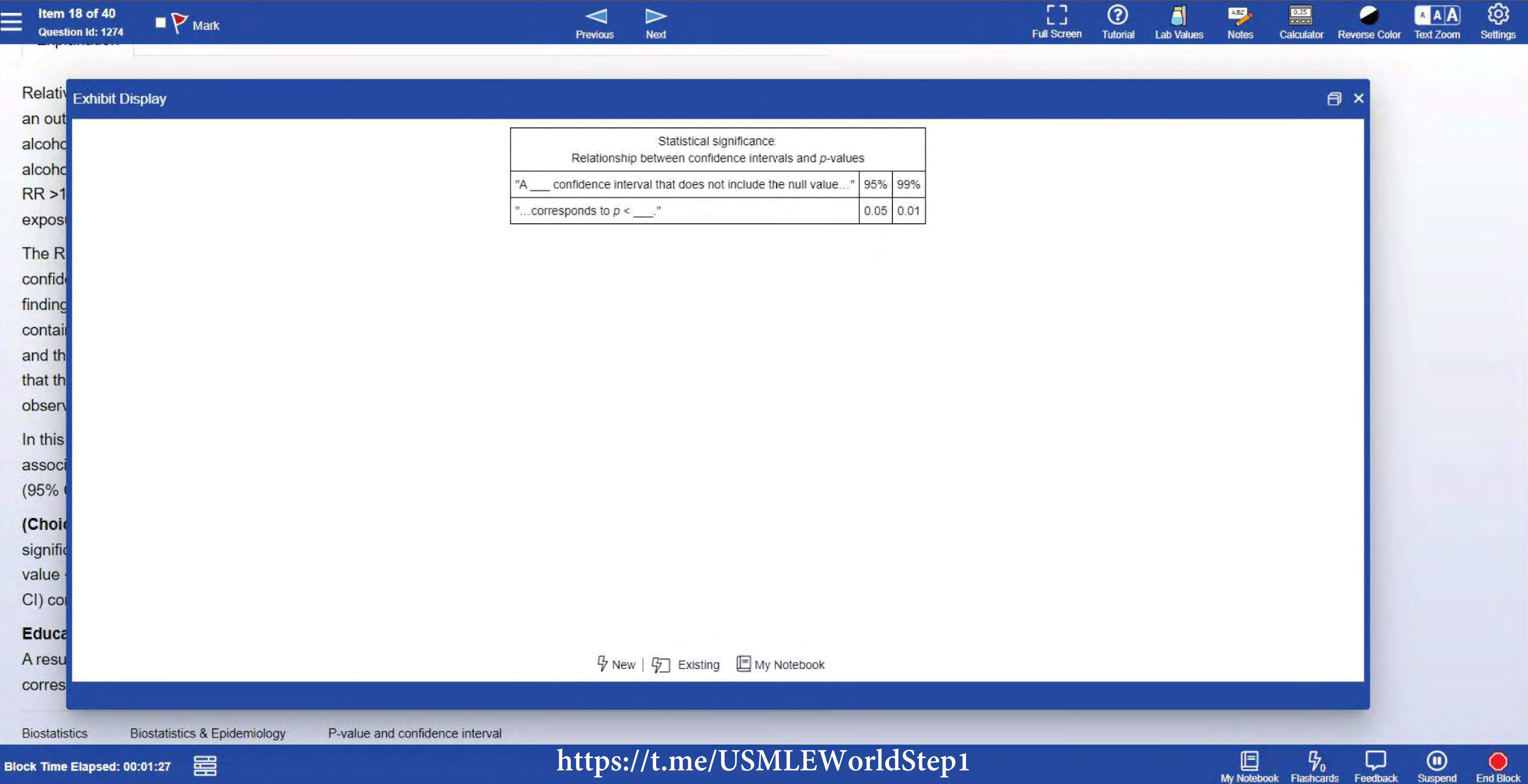
The RR by itself does not account for the possibility that chance alone is responsible for the results. The 95% confidence interval (CI) and p-value are 2 measures of **statistical significance** that can help strengthen the findings of a study using RR. For a result to be considered statistically significant, its corresponding CI must NOT contain the null value. When the **95% CI** does **not** include the null value, this gives a corresponding **p-value <0.05** and the association between exposure and outcome is considered statistically significant. A p-value <0.05 reflects that there is a very low probability that the result was due to chance alone; formally, the p-value is the probability of observing a given (or more extreme) result due to chance alone assuming that the null hypothesis is true.

In this example, the RR is 1.4 with a 95% CI of 1.02-1.85. It can be concluded that daily alcohol consumption is associated with an increased risk of breast carcinoma (RR >1) and that the findings are statistically significant (95% CI does not include the null value of 1.0). Therefore, the expected p-value would be <0.05.

(Choices B, C, D, and E) These options contain p-values >0.05, so the results would not be statistically significant. Note the relationship between CI and p-value: a statistically significant 95% CI corresponds to a p-value <0.05; a statistically significant 99% CI (would also not include the null value and likely be wider than a 95% CI) corresponds to a p-value <0.01.

Educational objective:
A result is considered statistically significant if the 95% confidence interval does not cross the null value, which corresponds to a p-value <0.05.

Biostatistics | Biostatistics & Epidemiology | P-value and confidence interval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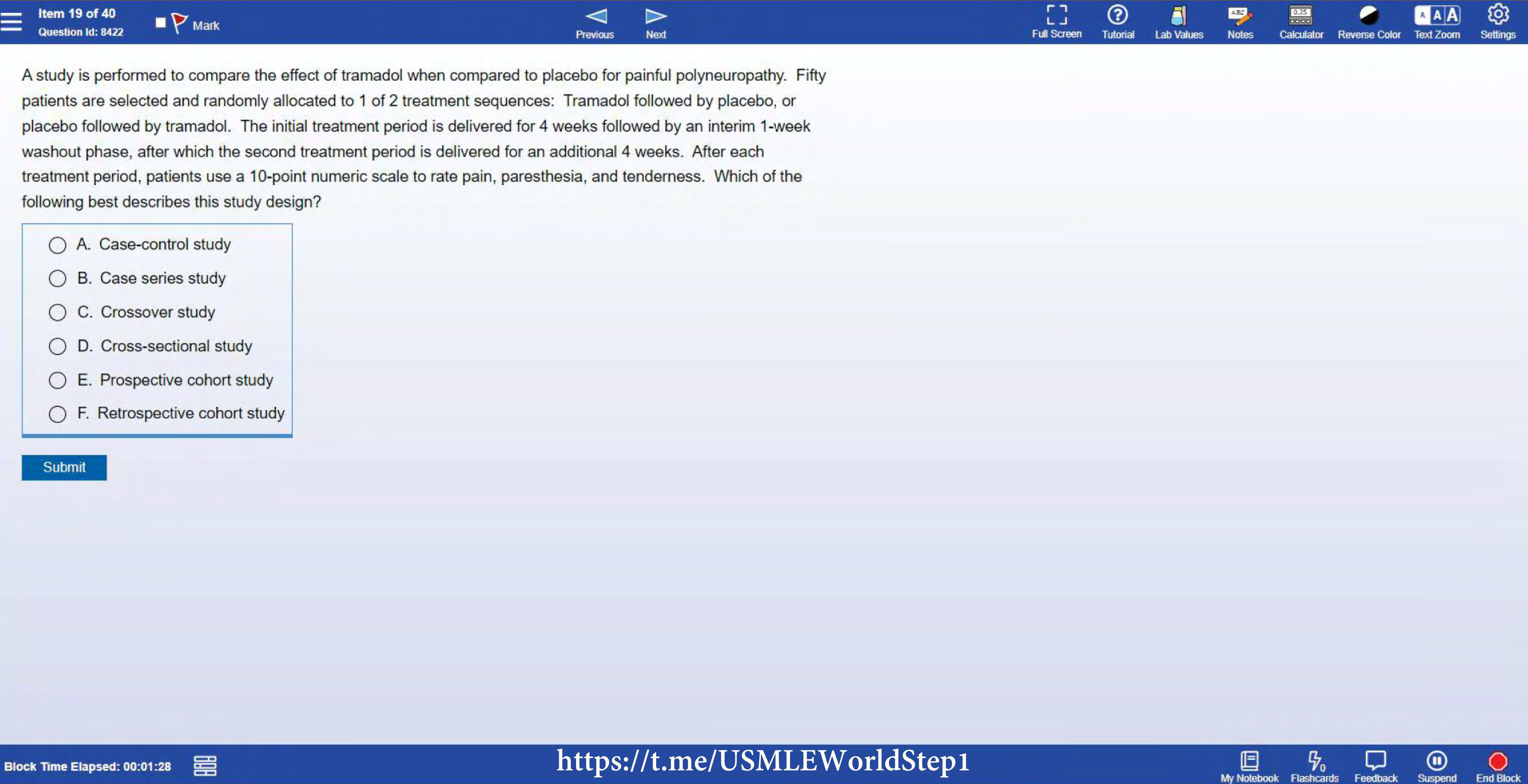
Statistical significance Relationship between confidence intervals and *p*-values		
"A ___ confidence interval that does not include the null value…"	95%	99%
"…corresponds to $p <$ ___."	0.05	0.01

Biostatistics

Biostatistics & Epidemiology

P-value and confidence interval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A study is performed to compare the effect of tramadol when compared to placebo for painful polyneuropathy. Fifty patients are selected and randomly allocated to 1 of 2 treatment sequences: Tramadol followed by placebo, or placebo followed by tramadol. The initial treatment period is delivered for 4 weeks followed by an interim 1-week washout phase, after which the second treatment period is delivered for an additional 4 weeks. After each treatment period, patients use a 10-point numeric scale to rate pain, paresthesia, and tenderness. Which of the following best describes this study design?

○ A. Case-control study
○ B. Case series study
○ C. Crossover study
○ D. Cross-sectional study
○ E. Prospective cohort study
○ F. Retrospective cohort study

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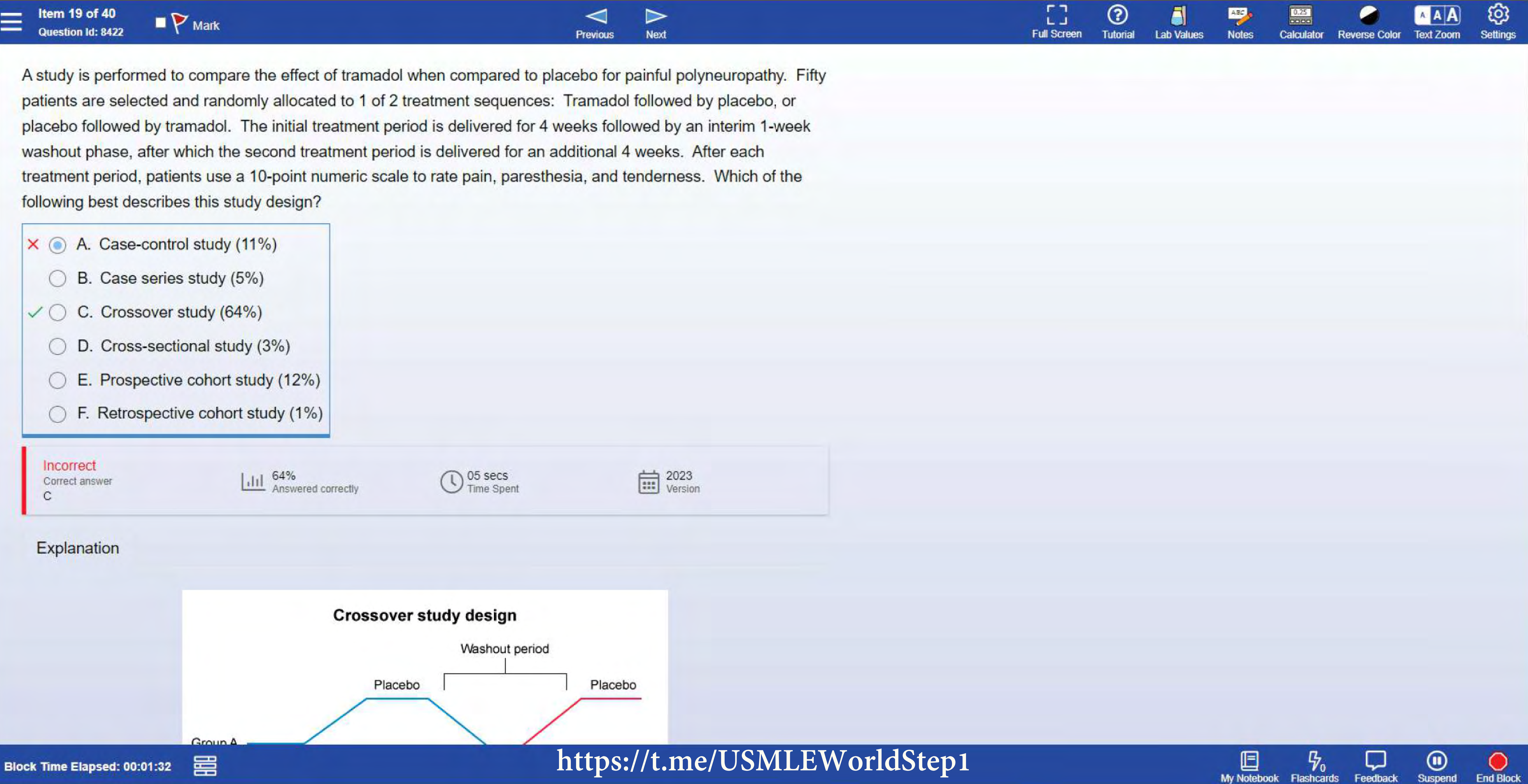
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- ✗ ● A. Case-control study (11%)
- ○ B. Case series study (5%)
- ✓ ○ C. Crossover study (64%)
- ○ D. Cross-sectional study (3%)
- ○ E. Prospective cohort study (12%)
- ○ F. Retrospective cohort study (1%)

Incorrect
Correct answer
C

64%
Answered correctly

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Explanation

Crossover study design

Washout period
Placebo
Placebo
Group A

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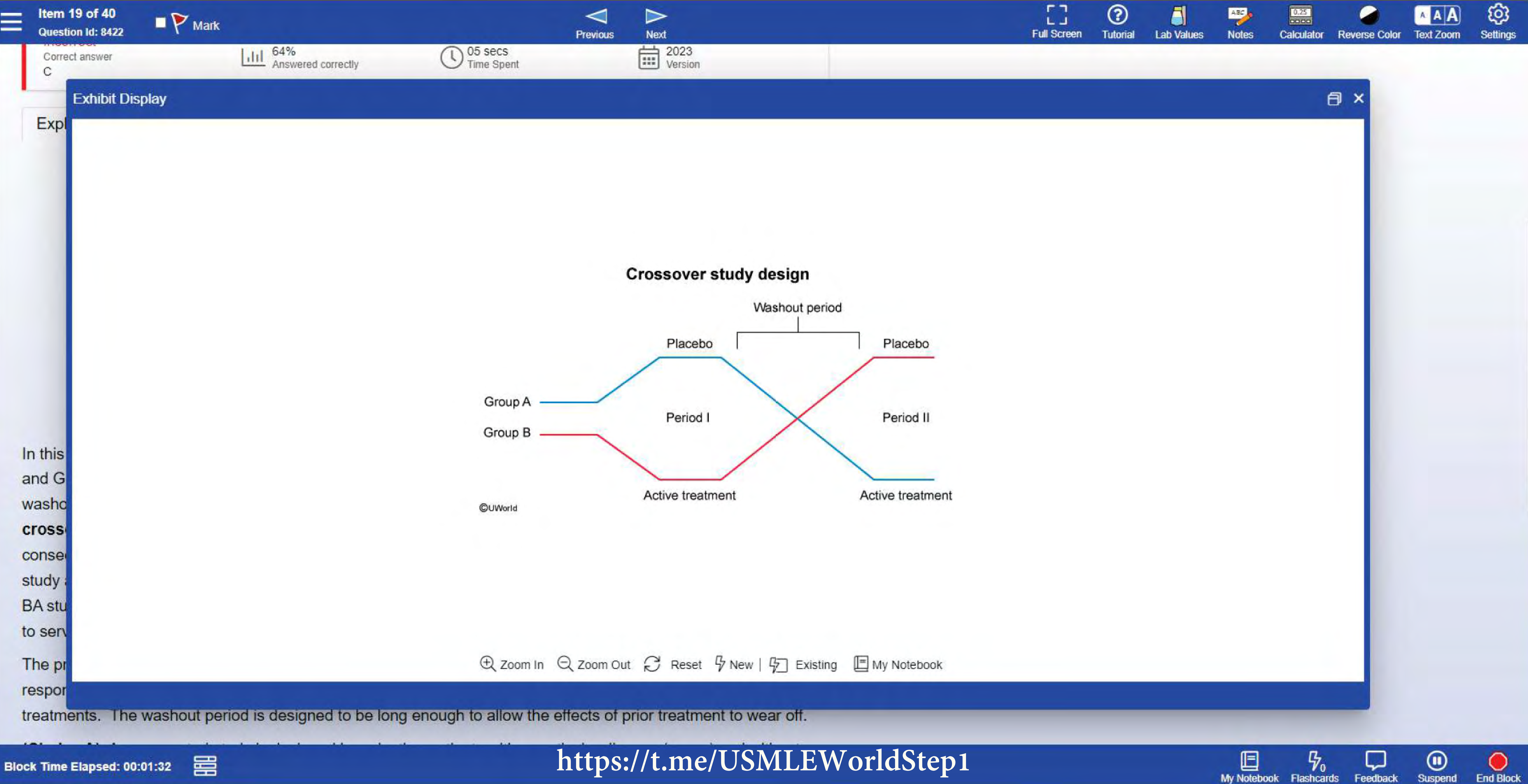
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Correct answer
C

64%
Answered correctly

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Expl

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Crossover study design

Washout period
Placebo
Placebo
Group A
Group B
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Period II
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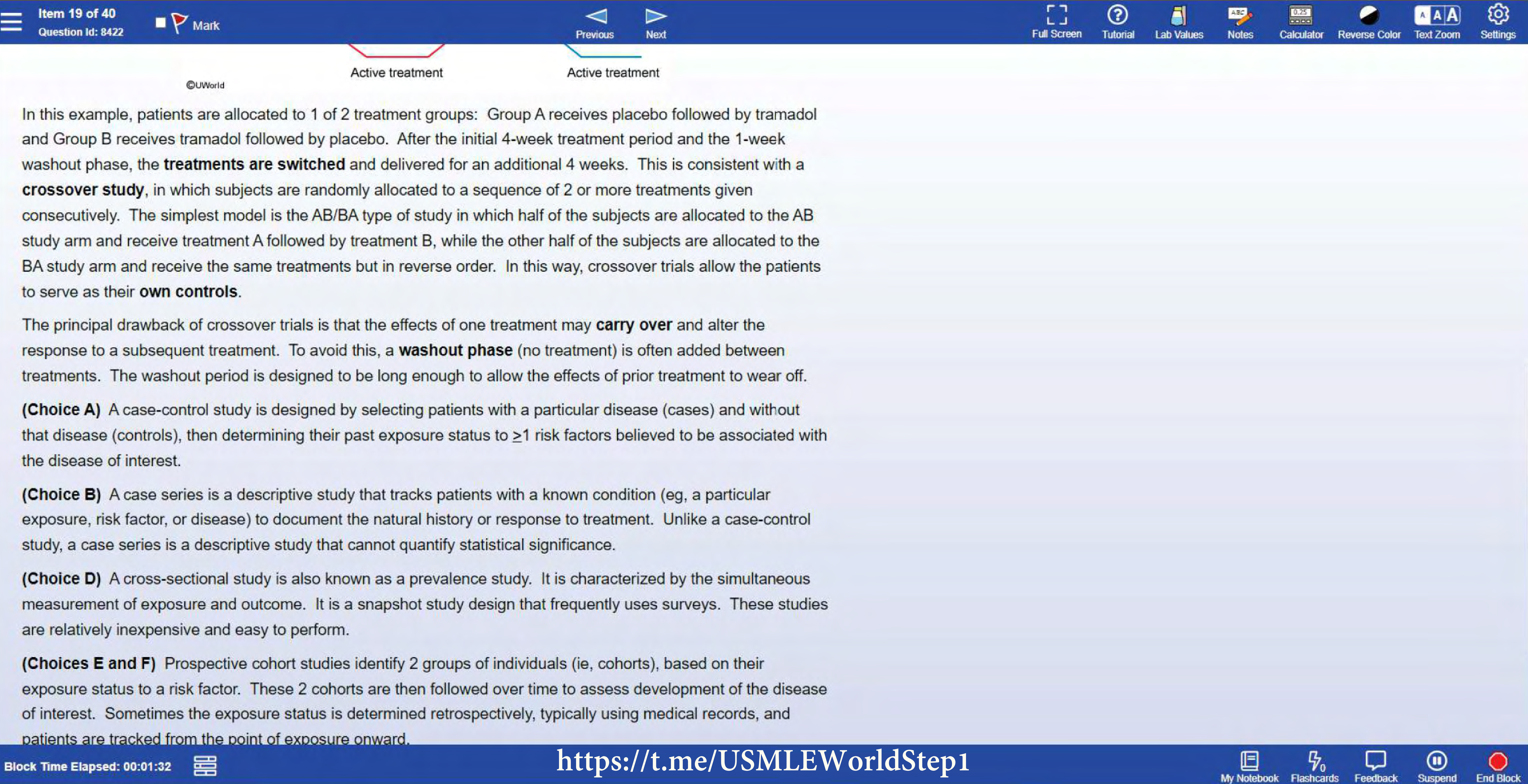


In this example, patients are allocated to 1 of 2 treatment groups: Group A receives placebo followed by tramadol and Group B receives tramadol followed by placebo. After the initial 4-week treatment period and the 1-week washout phase, the **treatments are switched** and delivered for an additional 4 weeks. This is consistent with a **crossover study**, in which subjects are randomly allocated to a sequence of 2 or more treatments given consecutively. The simplest model is the AB/BA type of study in which half of the subjects are allocated to the AB study arm and receive treatment A followed by treatment B, while the other half of the subjects are allocated to the BA study arm and receive the same treatments but in reverse order. In this way, crossover trials allow the patients to serve as their **own controls**.

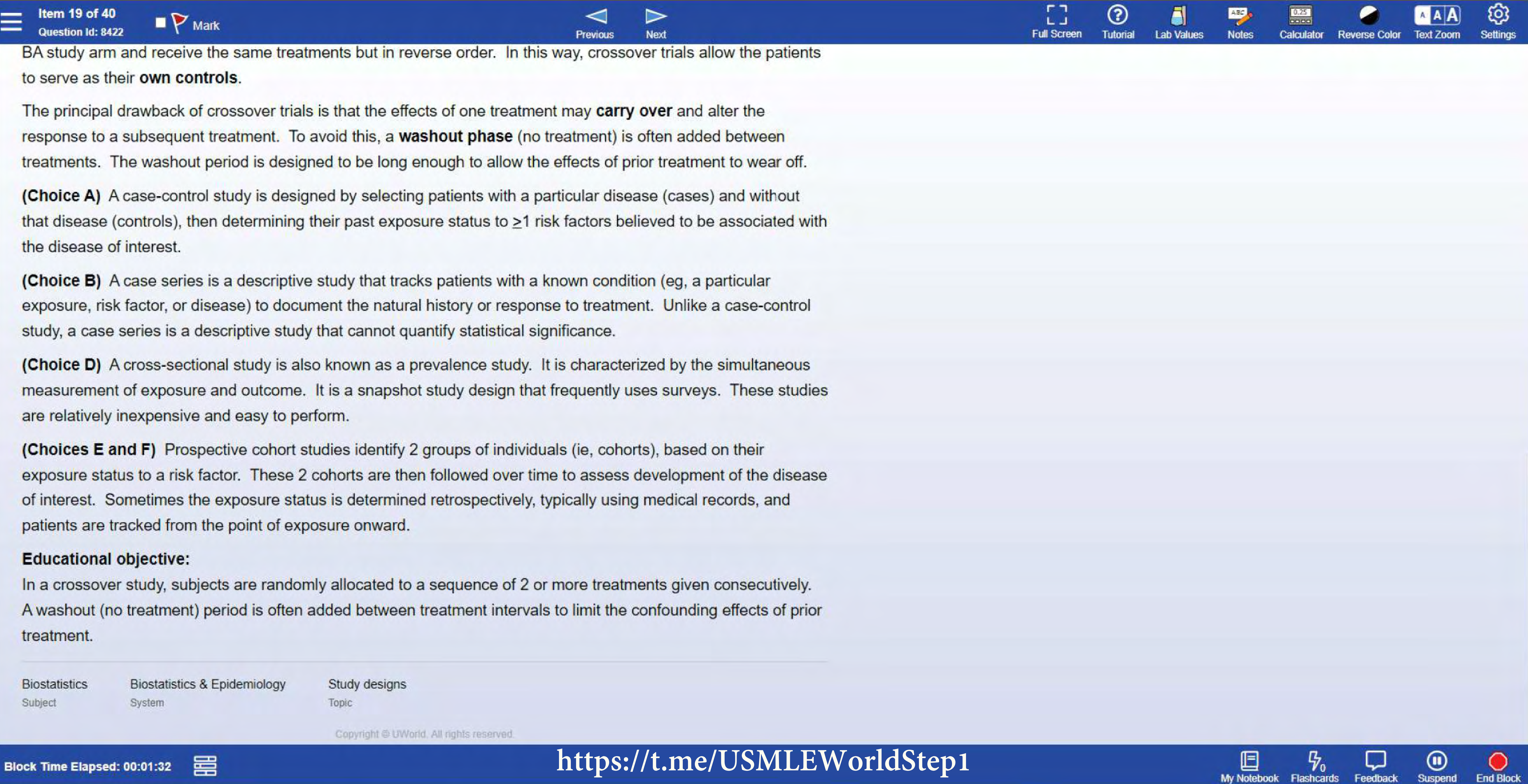
The principal drawback of crossover trials is that the effects of one treatment may **carry over** and alter the response to a subsequent treatment. To avoid this, a **washout phase** (no treatment) is often added between treatments. The washout period is designed to be long enough to allow the effects of prior treatment to wear off.

(Choice A) A case-control study is designed by selecting patients with a particular disease (cases) and without that disease (controls), then determining their past exposure status to $\geq$1 risk factors believed to be associated with the disease of interest.

(Choice B) A case series is a descriptive study that tracks patients with a known condition (eg, a particular exposure, risk factor, or disease) to document the natural history or response to treatment. Unlike a case-control study, a case series is a descriptive study that cannot quantify statistical significance.

(Choice D) A cross-sectional study is also known as a prevalence study. It is characterized by the simultaneous measurement of exposure and outcome. It is a snapshot study design that frequently uses surveys. These studies are relatively inexpensive and easy to perform.

(Choices E and F) Prospective cohort studies identify 2 groups of individuals (ie, cohorts), based on their exposure status to a risk factor. These 2 cohorts are then followed over time to assess development of the disease of interest. Sometimes the exposure status is determined retrospectively, typically using medical records, and patients are tracked from the point of exposure onward.



BA study arm and receive the same treatments but in reverse order. In this way, crossover trials allow the patients to serve as their **own controls**.

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Educational objective:

In a crossover study, subjects are randomly allocated to a sequence of 2 or more treatments given consecutively. A washout (no treatment) period is often added between treatment intervals to limit the confounding effects of prior treatment.

Biostatistics	Biostatistics & Epidemiology	Study designs
Subject	System	Topic

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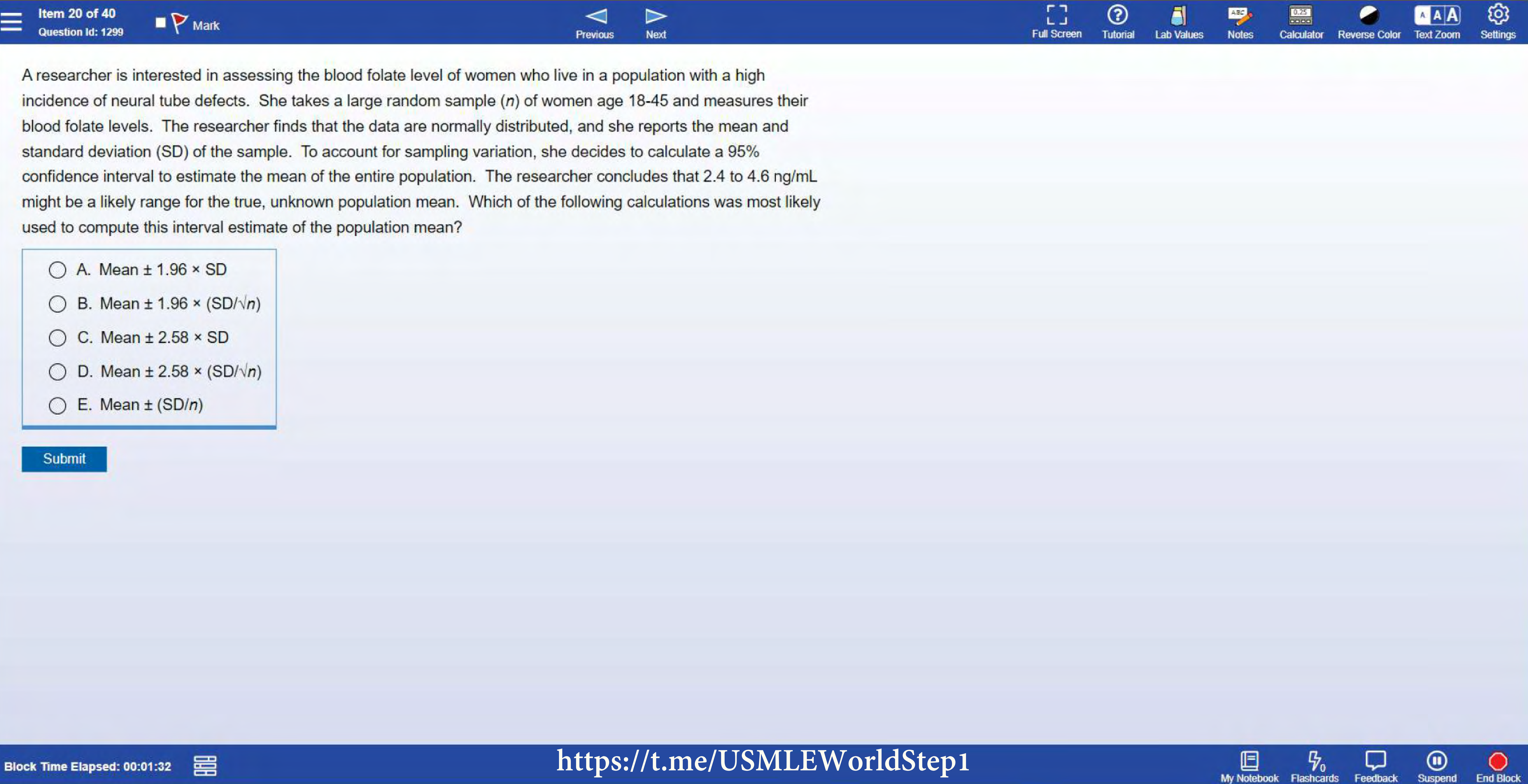
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A researcher is interested in assessing the blood folate level of women who live in a population with a high incidence of neural tube defects. She takes a large random sample (*n*) of women age 18-45 and measures their blood folate levels. The researcher finds that the data are normally distributed, and she reports the mean and standard deviation (SD) of the sample. To account for sampling variation, she decides to calculate a 95% confidence interval to estimate the mean of the entire population. The researcher concludes that 2.4 to 4.6 ng/mL might be a likely range for the true, unknown population mean. Which of the following calculations was most likely used to compute this interval estimate of the population mean?

○ A. Mean ± 1.96 × SD
○ B. Mean ± 1.96 × (SD/$\sqrt{n}$)
○ C. Mean ± 2.58 × SD
○ D. Mean ± 2.58 × (SD/$\sqrt{n}$)
○ E. Mean ± (SD/*n*)

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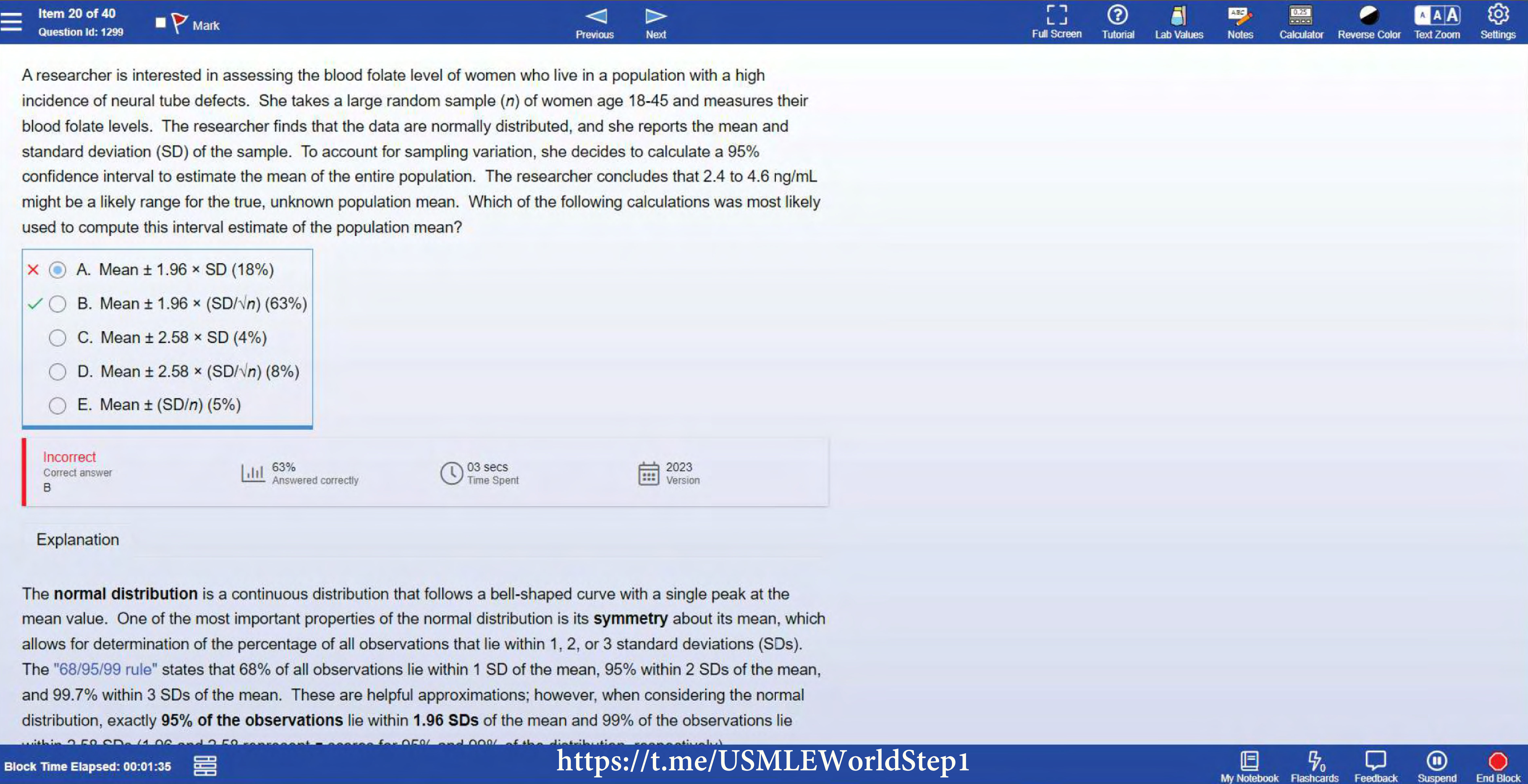
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A researcher is interested in assessing the blood folate level of women who live in a population with a high incidence of neural tube defects. She takes a large random sample (*n*) of women age 18-45 and measures their blood folate levels. The researcher finds that the data are normally distributed, and she reports the mean and standard deviation (SD) of the sample. To account for sampling variation, she decides to calculate a 95% confidence interval to estimate the mean of the entire population. The researcher concludes that 2.4 to 4.6 ng/mL might be a likely range for the true, unknown population mean. Which of the following calculations was most likely used to compute this interval estimate of the population mean?

- ✗ ● A. Mean ± 1.96 × SD (18%)
- ✓ ○ B. Mean ± 1.96 × (SD/√*n*) (63%)
- ○ C. Mean ± 2.58 × SD (4%)
- ○ D. Mean ± 2.58 × (SD/√*n*) (8%)
- ○ E. Mean ± (SD/*n*) (5%)

Incorrect
Correct answer
B

63%
Answered correctly

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Explanation

The **normal distribution** is a continuous distribution that follows a bell-shaped curve with a single peak at the mean value. One of the most important properties of the normal distribution is its **symmetry** about its mean, which allows for determination of the percentage of all observations that lie within 1, 2, or 3 standard deviations (SDs). The "68/95/99 rule" states that 68% of all observations lie within 1 SD of the mean, 95% within 2 SDs of the mean, and 99.7% within 3 SDs of the mean. These are helpful approximations; however, when considering the normal distribution, exactly **95% of the observations** lie within **1.96 SDs** of the mean and 99% of the observations lie within 2.58 SDs (1.96 and 2.58 represent z-scores for 95% and 99% of the distribution, respectively).

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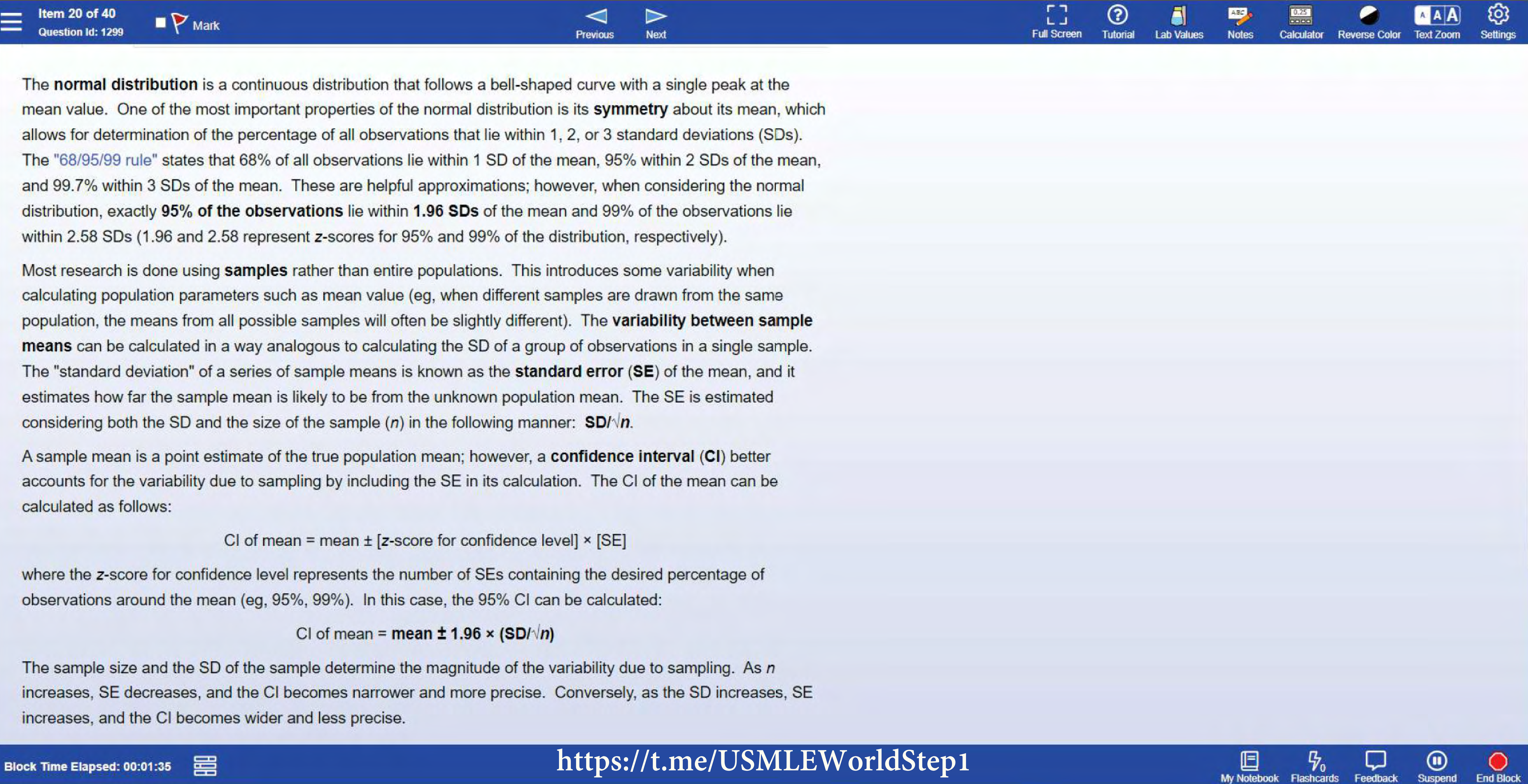


The **normal distribution** is a continuous distribution that follows a bell-shaped curve with a single peak at the mean value. One of the most important properties of the normal distribution is its **symmetry** about its mean, which allows for determination of the percentage of all observations that lie within 1, 2, or 3 standard deviations (SDs). The "68/95/99 rule" states that 68% of all observations lie within 1 SD of the mean, 95% within 2 SDs of the mean, and 99.7% within 3 SDs of the mean. These are helpful approximations; however, when considering the normal distribution, exactly **95% of the observations** lie within **1.96 SDs** of the mean and 99% of the observations lie within 2.58 SDs (1.96 and 2.58 represent ***z***-scores for 95% and 99% of the distribution, respectively).

Most research is done using **samples** rather than entire populations. This introduces some variability when calculating population parameters such as mean value (eg, when different samples are drawn from the same population, the means from all possible samples will often be slightly different). The **variability between sample means** can be calculated in a way analogous to calculating the SD of a group of observations in a single sample. The "standard deviation" of a series of sample means is known as the **standard error** (**SE**) of the mean, and it estimates how far the sample mean is likely to be from the unknown population mean. The SE is estimated considering both the SD and the size of the sample (n) in the following manner: $\mathbf{SD/\sqrt{n}}$.

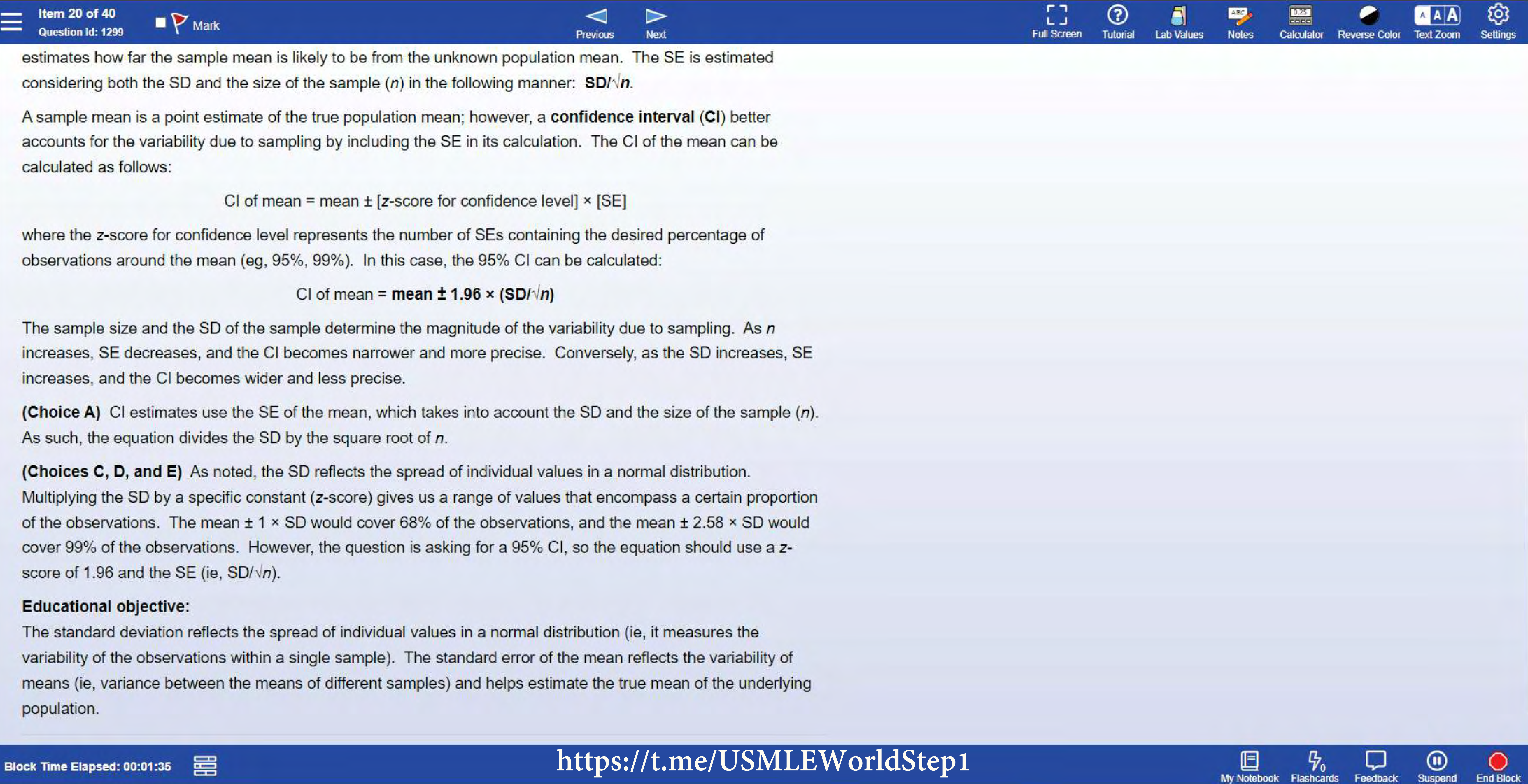
A sample mean is a point estimate of the true population mean; however, a **confidence interval** (**CI**) better accounts for the variability due to sampling by including the SE in its calculation. The CI of the mean can be calculated as follows:

$$\text{CI of mean} = \text{mean} \pm [z\text{-score for confidence level}] \times [\text{SE}]$$

where the ***z***-score for confidence level represents the number of SEs containing the desired percentage of observations around the mean (eg, 95%, 99%). In this case, the 95% CI can be calculated:

$$\text{CI of mean} = \mathbf{mean \pm 1.96 \times (SD/\sqrt{n})}$$

The sample size and the SD of the sample determine the magnitude of the variability due to sampling. As n increases, SE decreases, and the CI becomes narrower and more precise. Conversely, as the SD increases, SE increases, and the CI becomes wider and less precise.



estimates how far the sample mean is likely to be from the unknown population mean. The SE is estimated considering both the SD and the size of the sample (*n*) in the following manner: **SD/√*n***.

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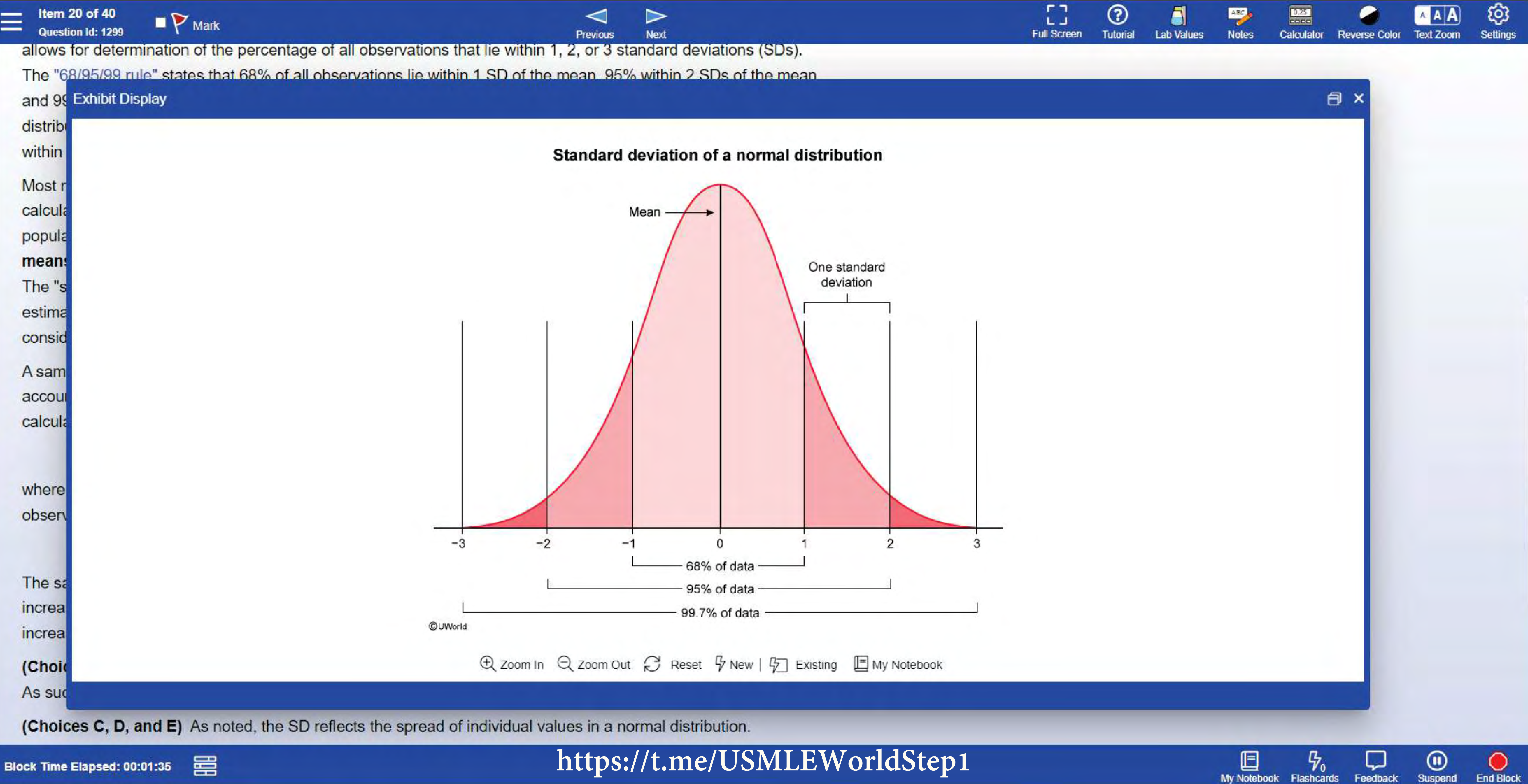
The sample size and the SD of the sample determine the magnitude of the variability due to sampling. As *n* increases, SE decreases, and the CI becomes narrower and more precise. Conversely, as the SD increases, SE increases, and the CI becomes wider and less precise.

(Choice A) CI estimates use the SE of the mean, which takes into account the SD and the size of the sample (*n*). As such, the equation divides the SD by the square root of *n*.

(Choices C, D, and E) As noted, the SD reflects the spread of individual values in a normal distribution. Multiplying the SD by a specific constant (***z***-score) gives us a range of values that encompass a certain proportion of the observations. The mean ± 1 × SD would cover 68% of the observations, and the mean ± 2.58 × SD would cover 99% of the observations. However, the question is asking for a 95% CI, so the equation should use a ***z***-score of 1.96 and the SE (ie, SD/√*n*).

Educational objective:

The standard deviation reflects the spread of individual values in a normal distribution (ie, it measures the variability of the observations within a single sample). The standard error of the mean reflects the variability of means (ie, variance between the means of different samples) and helps estimate the true mean of the underlying population.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The "68/95/99 rule" states that 68% of all observations lie within 1 SD of the mean, 95% within 2 SDs of the mean
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Standard deviation of a normal distribution

Mean
One standard deviation
−3
−2
−1
0
1
2
3
68% of data
95% of data
99.7% of data
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(Choices C, D, and E) As noted, the SD reflects the spread of individual values in a normal distribution.

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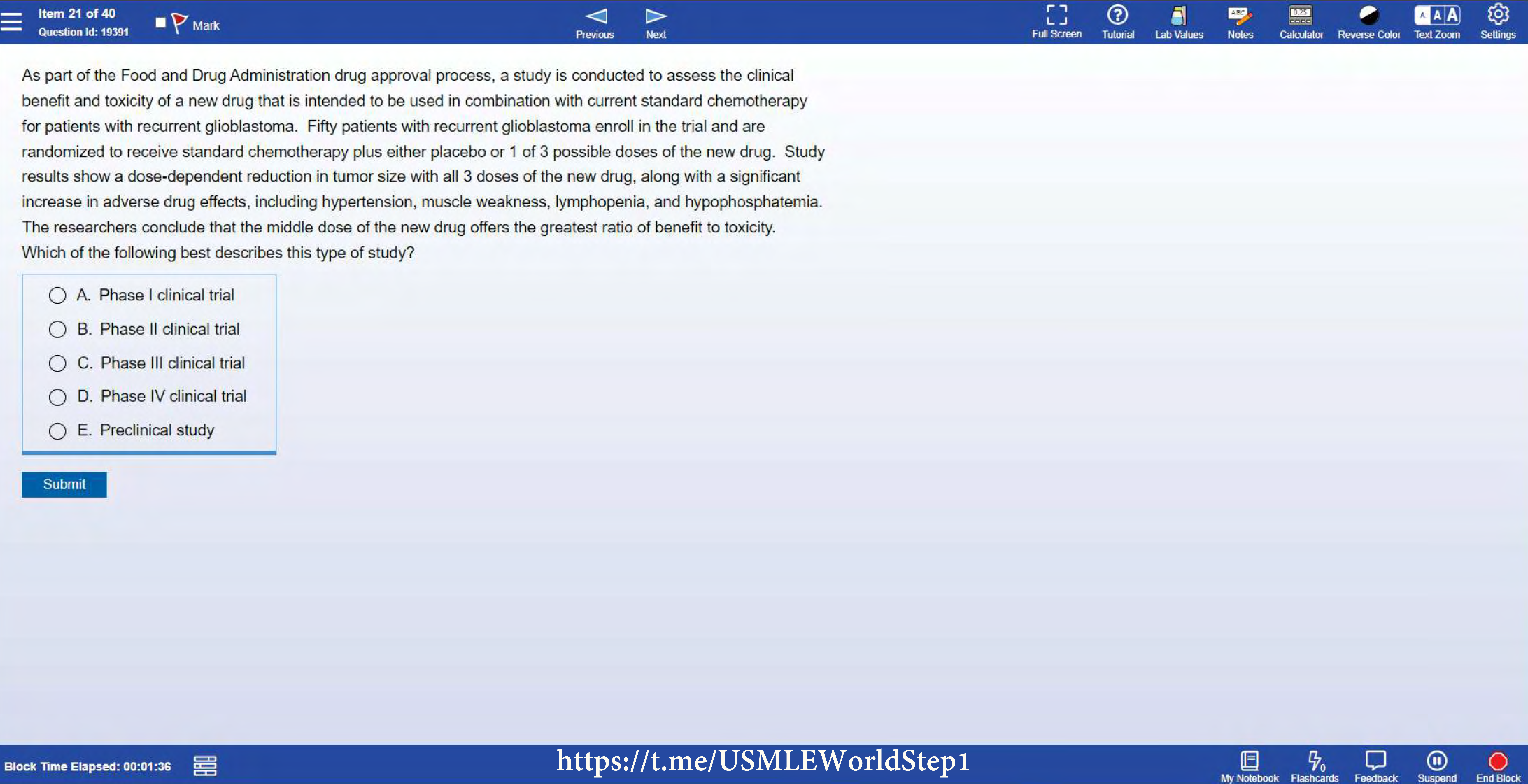
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As part of the Food and Drug Administration drug approval process, a study is conducted to assess the clinical benefit and toxicity of a new drug that is intended to be used in combination with current standard chemotherapy for patients with recurrent glioblastoma. Fifty patients with recurrent glioblastoma enroll in the trial and are randomized to receive standard chemotherapy plus either placebo or 1 of 3 possible doses of the new drug. Study results show a dose-dependent reduction in tumor size with all 3 doses of the new drug, along with a significant increase in adverse drug effects, including hypertension, muscle weakness, lymphopenia, and hypophosphatemia. The researchers conclude that the middle dose of the new drug offers the greatest ratio of benefit to toxicity. Which of the following best describes this type of study?

○ A. Phase I clinical trial
○ B. Phase II clinical trial
○ C. Phase III clinical trial
○ D. Phase IV clinical trial
○ E. Preclinical study

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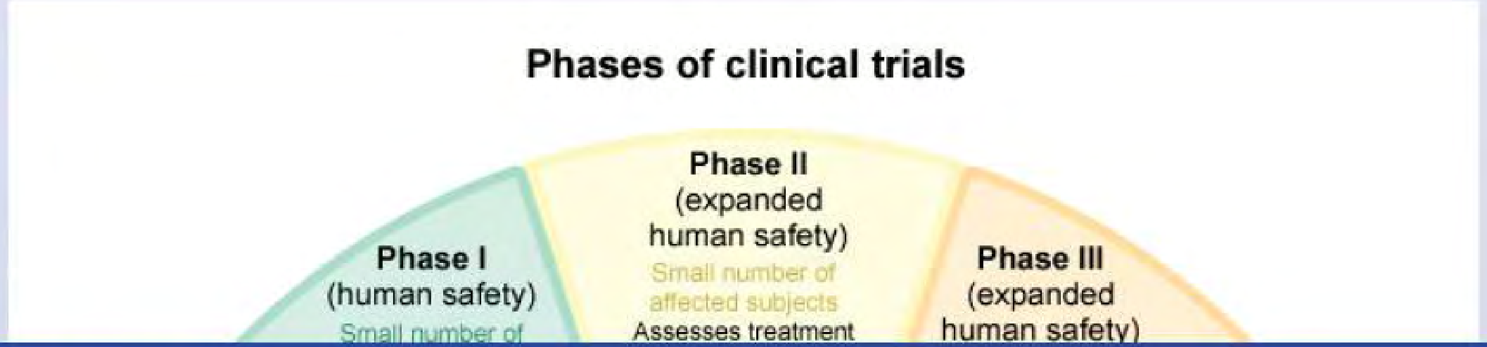
○ A. Phase I clinical trial (12%)
✓ ● B. Phase II clinical trial (48%)
○ C. Phase III clinical trial (31%)
○ D. Phase IV clinical trial (6%)
○ E. Preclinical study (0%)

Correct | 48% Answered correctly | 07 secs Time Spent | 2023 Version

Explanation



Phases of clinical trials

Phase I
(human safety)
Small number of
Phase II
(expanded
human safety)
Small number of
affected subjects
Assesses treatment
Phase III
(expanded
human safety)

Correct 48% 07 secs 2023

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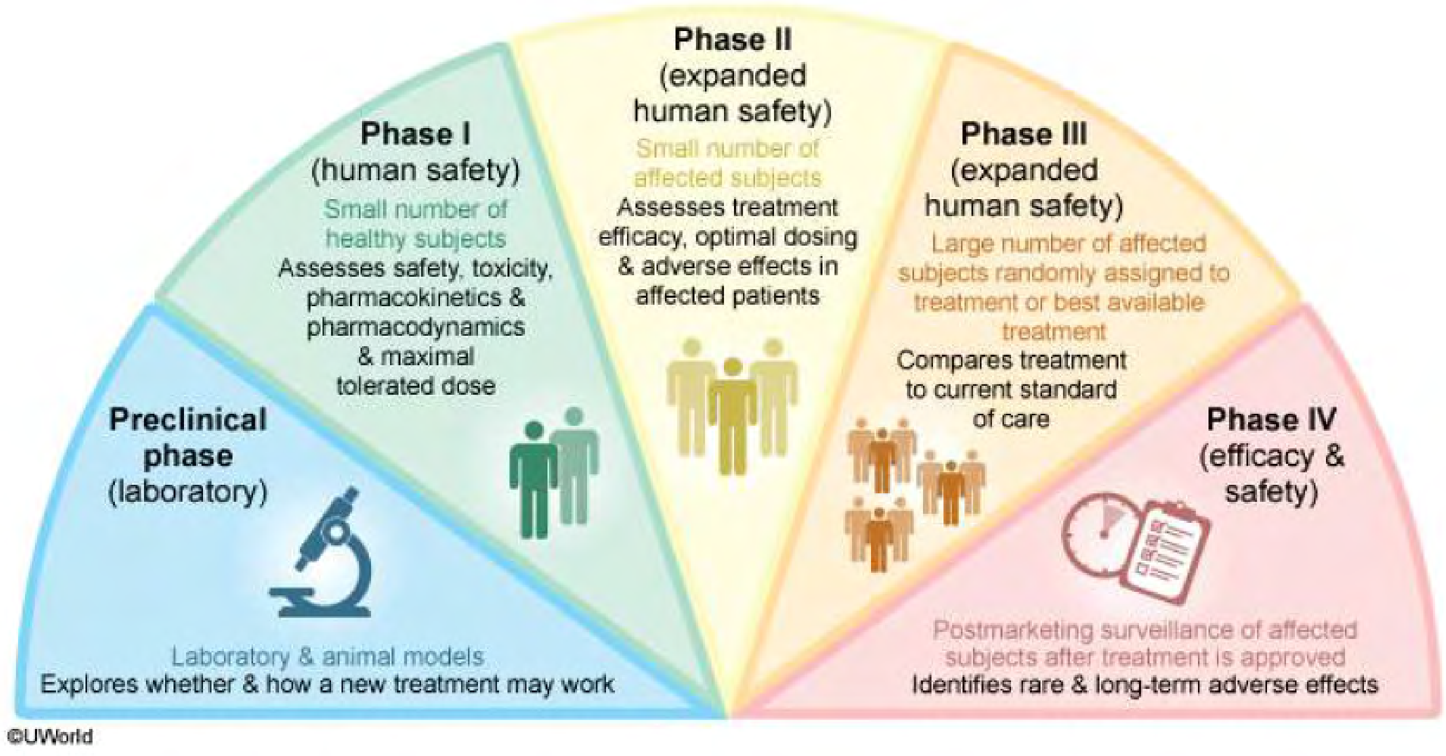
Phases of clinical trials



Preclinical phase (laboratory)
Laboratory & animal models
Explores whether & how a new treatment may work

Phase I (human safety)
Small number of healthy subjects
Assesses safety, toxicity, pharmacokinetics & pharmacodynamics & maximal tolerated dose

Phase II (expanded human safety)
Small number of affected subjects
Assesses treatment efficacy, optimal dosing & adverse effects in affected patients

Phase III (expanded human safety)
Large number of affected subjects randomly assigned to treatment or best available treatment
Compares treatment to current standard of care

Phase IV (efficacy & safety)
Postmarketing surveillance of affected subjects after treatment is approved
Identifies rare & long-term adverse effects

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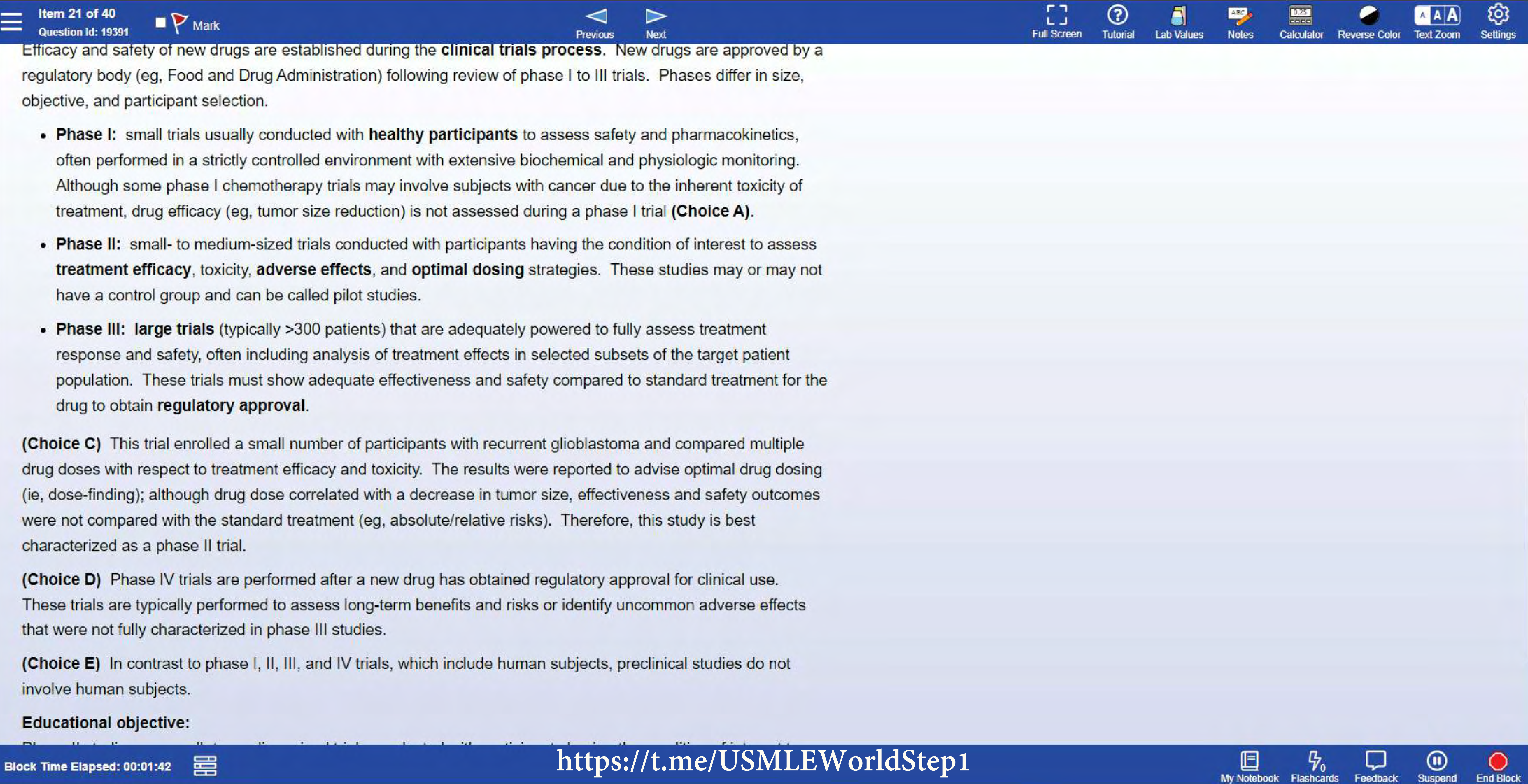
treatment, drug efficacy (eg, tumor size reduction) is not assessed during a phase I trial **(Choice A)**.



Efficacy and safety of new drugs are established during the **clinical trials process**. New drugs are approved by a regulatory body (eg, Food and Drug Administration) following review of phase I to III trials. Phases differ in size, objective, and participant selection.

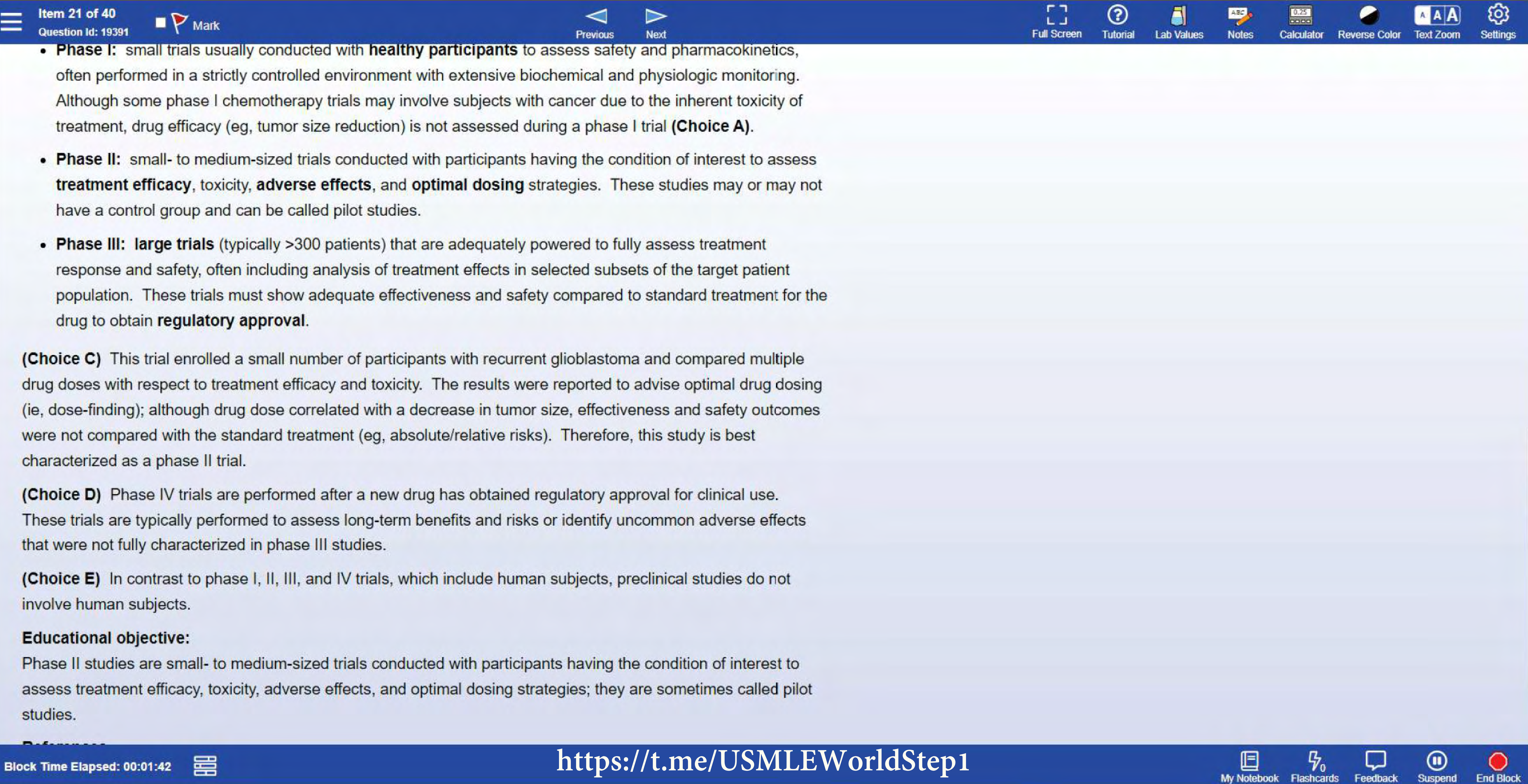
- **Phase I:** small trials usually conducted with **healthy participants** to assess safety and pharmacokinetics, often performed in a strictly controlled environment with extensive biochemical and physiologic monitoring. Although some phase I chemotherapy trials may involve subjects with cancer due to the inherent toxicity of treatment, drug efficacy (eg, tumor size reduction) is not assessed during a phase I trial **(Choice A)**.
- **Phase II:** small- to medium-sized trials conducted with participants having the condition of interest to assess **treatment efficacy**, toxicity, **adverse effects**, and **optimal dosing** strategies. These studies may or may not have a control group and can be called pilot studies.
- **Phase III:** **large trials** (typically >300 patients) that are adequately powered to fully assess treatment response and safety, often including analysis of treatment effects in selected subsets of the target patient population. These trials must show adequate effectiveness and safety compared to standard treatment for the drug to obtain **regulatory approval**.

(Choice C) This trial enrolled a small number of participants with recurrent glioblastoma and compared multiple drug doses with respect to treatment efficacy and toxicity. The results were reported to advise optimal drug dosing (ie, dose-finding); although drug dose correlated with a decrease in tumor size, effectiveness and safety outcomes were not compared with the standard treatment (eg, absolute/relative risks). Therefore, this study is best characterized as a phase II trial.

(Choice D) Phase IV trials are performed after a new drug has obtained regulatory approval for clinical use. These trials are typically performed to assess long-term benefits and risks or identify uncommon adverse effects that were not fully characterized in phase III studies.

(Choice E) In contrast to phase I, II, III, and IV trials, which include human subjects, preclinical studies do not involve human subjects.

Educational objective:



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Educational objective:

Phase II studies are small- to medium-sized trials conducted with participants having the condition of interest to assess treatment efficacy, toxicity, adverse effects, and optimal dosing strategies; they are sometimes called pilot studies.

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A new biomarker has been shown to allow for the early detection of non-small cell lung carcinoma. A preliminary analysis on a cohort study of this new test demonstrates that its use prolongs survival of lung cancer patients by 3 months when compared to the survival of patients diagnosed by conventional methods. A secondary analysis reveals no difference in 6-month mortality rates between the 2 groups. Which of the following factors most likely explains the study results?

○ A. Confounding
○ B. Lead-time bias
○ C. Length-time bias
○ D. Measurement bias
○ E. Observer bias
○ F. Rare disease assumption

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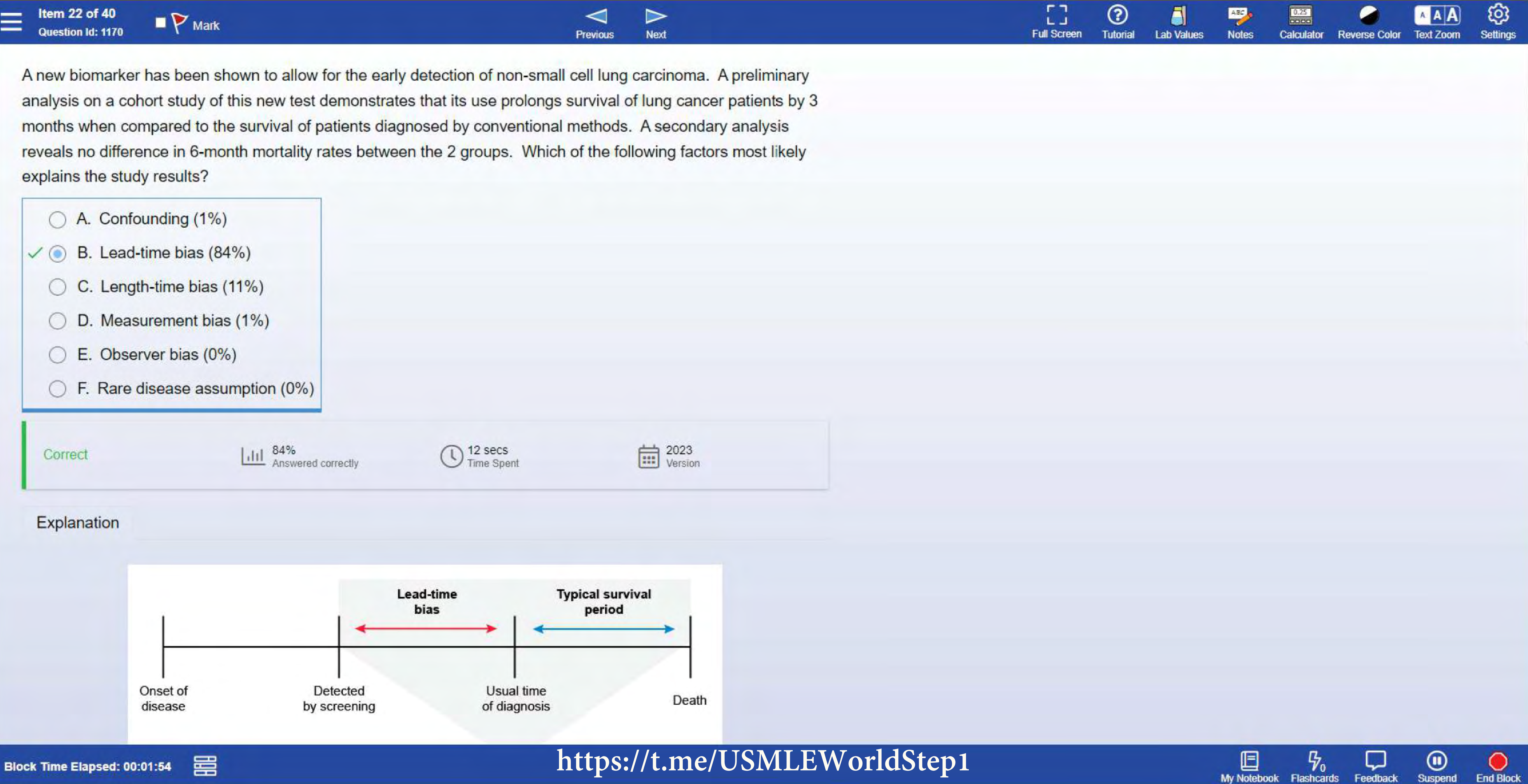
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- ○ A. Confounding (1%)
- ✓ ● B. Lead-time bias (84%)
- ○ C. Length-time bias (11%)
- ○ D. Measurement bias (1%)
- ○ E. Observer bias (0%)
- ○ F. Rare disease assumption (0%)

Correct

84% Answered correctly

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Explanation

Lead-time bias
Typical survival period
Onset of disease
Detected by screening
Usual time of diagnosis
Death
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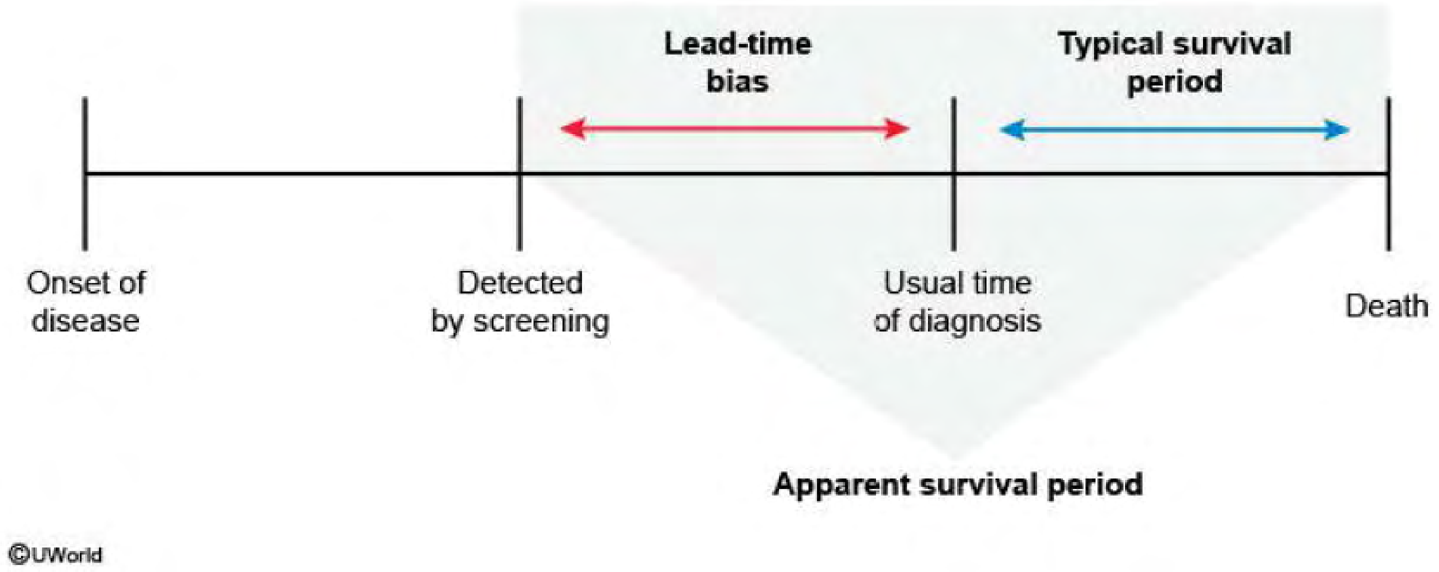
Lead-time bias
Typical survival period
Onset of disease
Detected by screening
Usual time of diagnosis
Death
Apparent survival period
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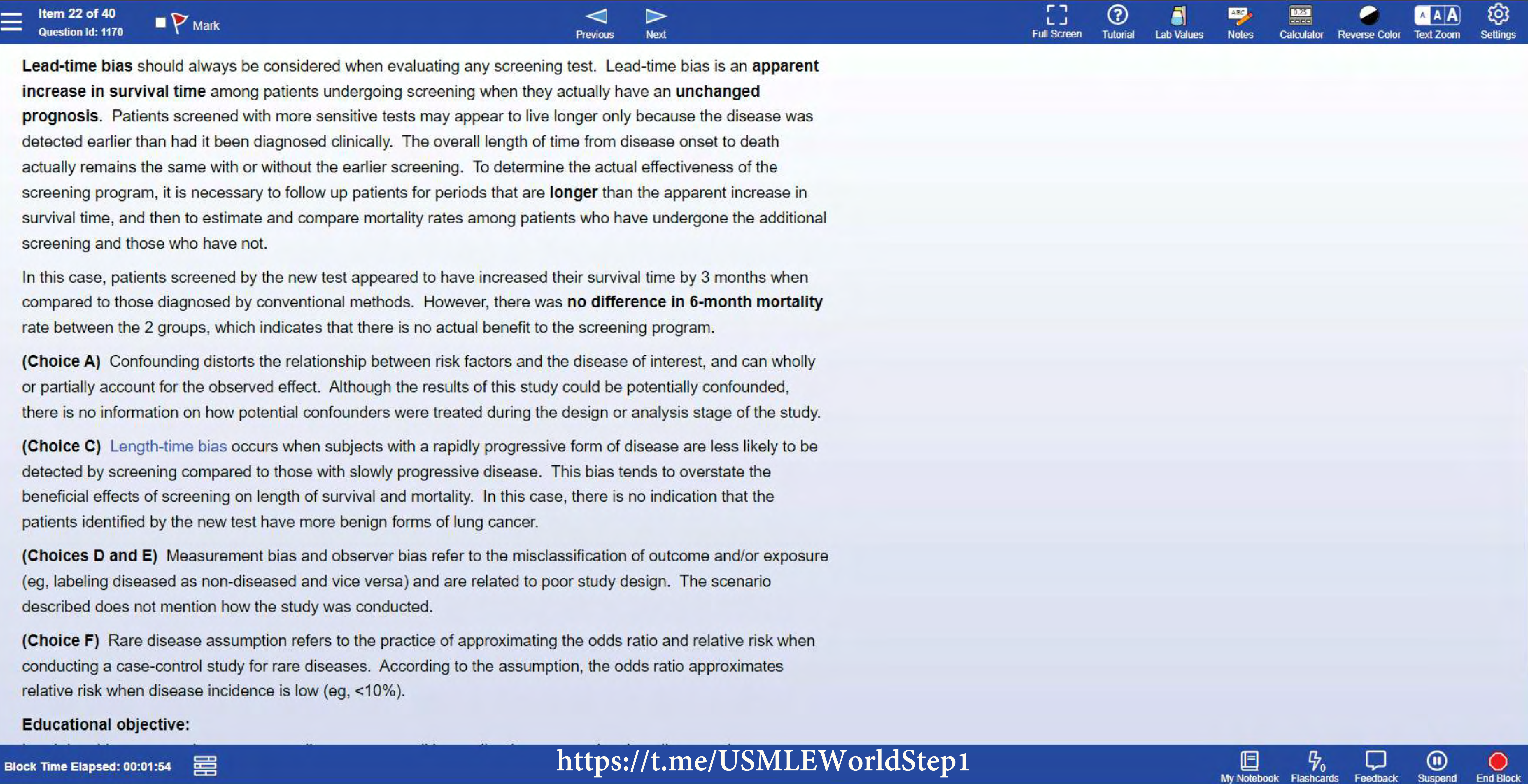
or partially account for the observed effect. Although the results of this study could be potentially confounded,



Lead-time bias should always be considered when evaluating any screening test. Lead-time bias is an **apparent increase in survival time** among patients undergoing screening when they actually have an **unchanged prognosis**. Patients screened with more sensitive tests may appear to live longer only because the disease was detected earlier than had it been diagnosed clinically. The overall length of time from disease onset to death actually remains the same with or without the earlier screening. To determine the actual effectiveness of the screening program, it is necessary to follow up patients for periods that are **longer** than the apparent increase in survival time, and then to estimate and compare mortality rates among patients who have undergone the additional screening and those who have not.

In this case, patients screened by the new test appeared to have increased their survival time by 3 months when compared to those diagnosed by conventional methods. However, there was **no difference in 6-month mortality** rate between the 2 groups, which indicates that there is no actual benefit to the screening program.

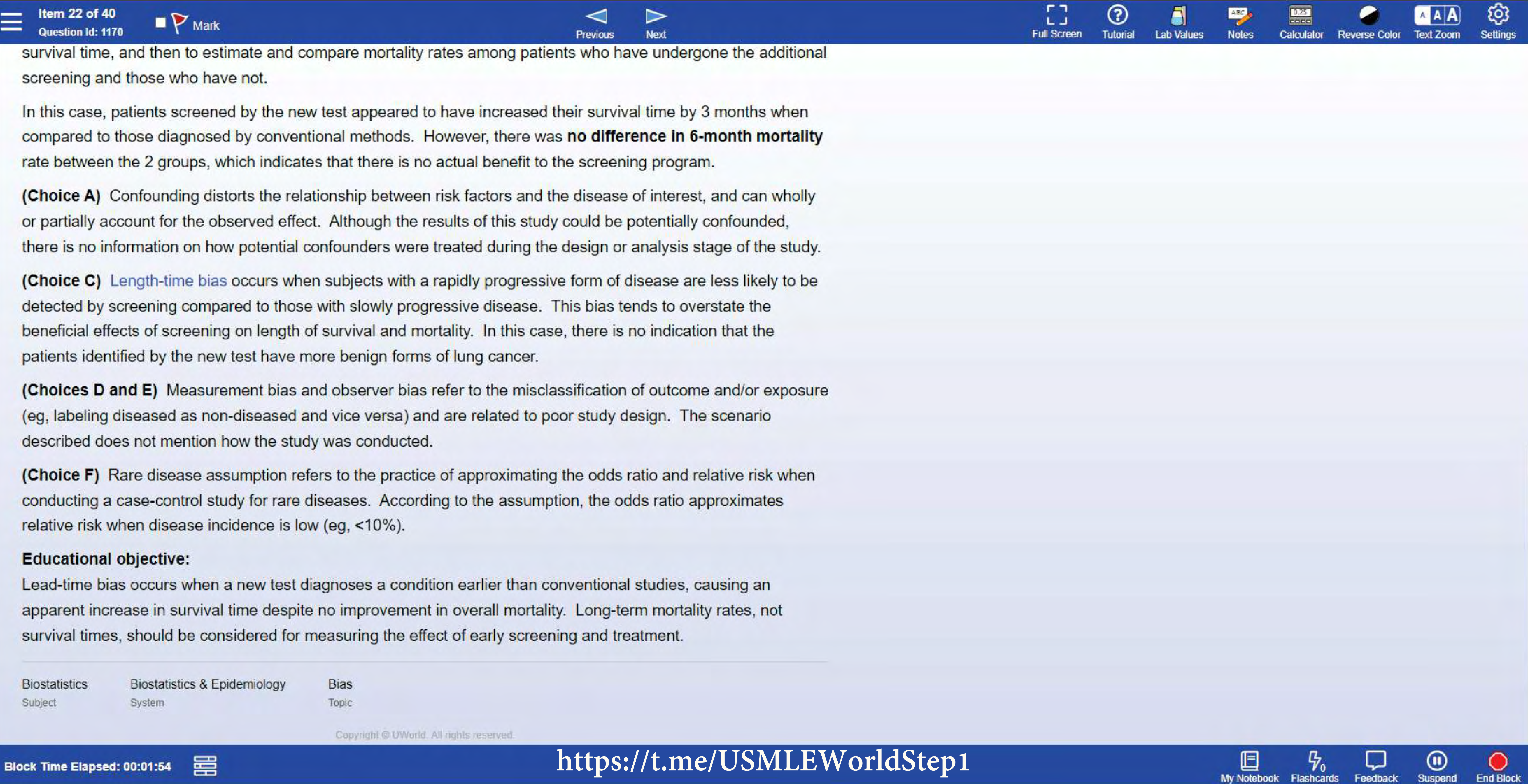
(Choice A) Confounding distorts the relationship between risk factors and the disease of interest, and can wholly or partially account for the observed effect. Although the results of this study could be potentially confounded, there is no information on how potential confounders were treated during the design or analysis stage of the study.

(Choice C) Length-time bias occurs when subjects with a rapidly progressive form of disease are less likely to be detected by screening compared to those with slowly progressive disease. This bias tends to overstate the beneficial effects of screening on length of survival and mortality. In this case, there is no indication that the patients identified by the new test have more benign forms of lung cancer.

(Choices D and E) Measurement bias and observer bias refer to the misclassification of outcome and/or exposure (eg, labeling diseased as non-diseased and vice versa) and are related to poor study design. The scenario described does not mention how the study was conducted.

(Choice F) Rare disease assumption refers to the practice of approximating the odds ratio and relative risk when conducting a case-control study for rare diseases. According to the assumption, the odds ratio approximates relative risk when disease incidence is low (eg, <10%).

Educational objective:



survival time, and then to estimate and compare mortality rates among patients who have undergone the additional screening and those who have not.

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Educational objective:

Lead-time bias occurs when a new test diagnoses a condition earlier than conventional studies, causing an apparent increase in survival time despite no improvement in overall mortality. Long-term mortality rates, not survival times, should be considered for measuring the effect of early screening and treatment.

Biostatistics	Biostatistics & Epidemiology	Bias
Subject	System	Topic

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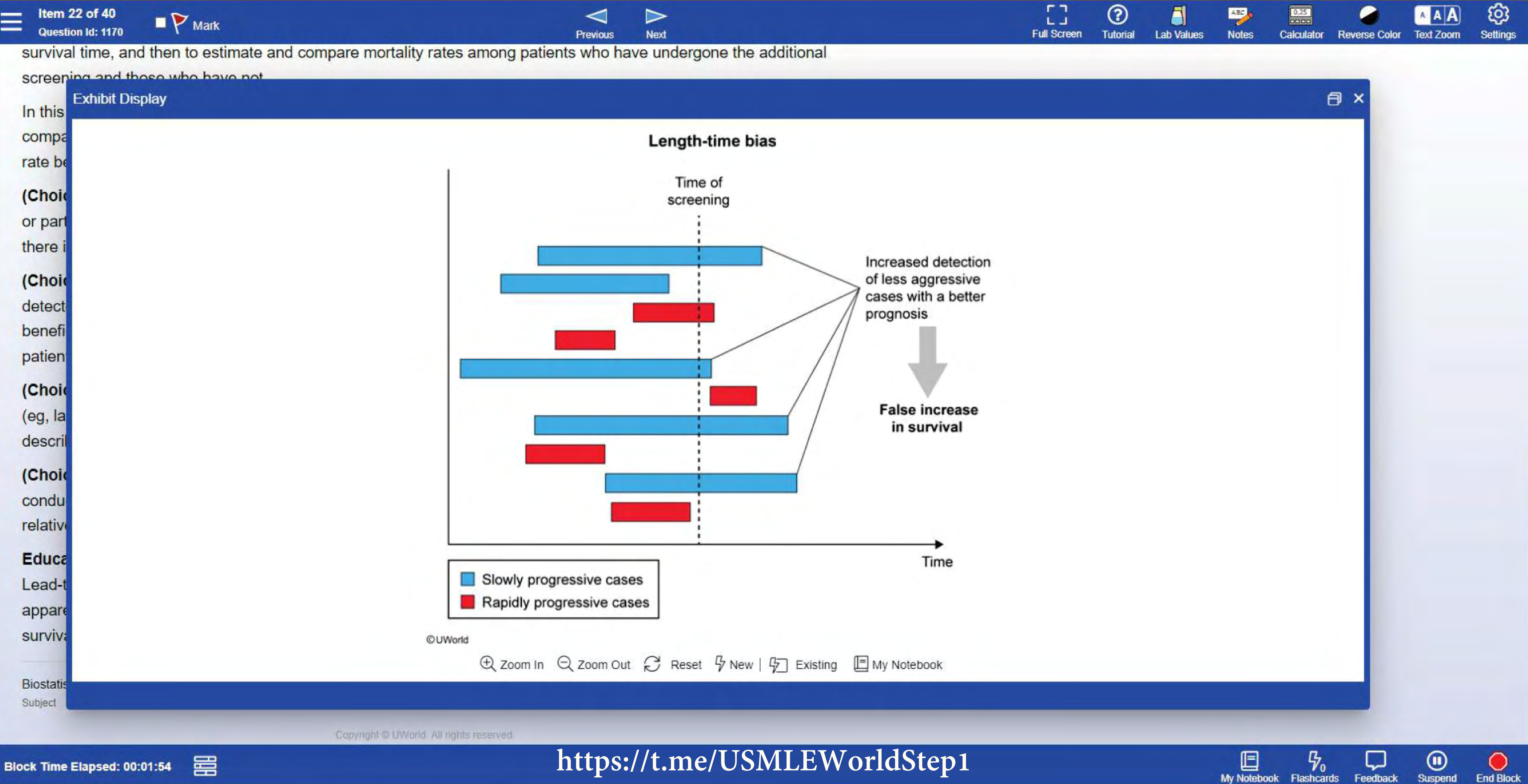
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Length-time bias
Time of screening
Increased detection of less aggressive cases with a better prognosis
False increase in survival
Time
🟦 Slowly progressive cases
🟥 Rapidly progressive cases
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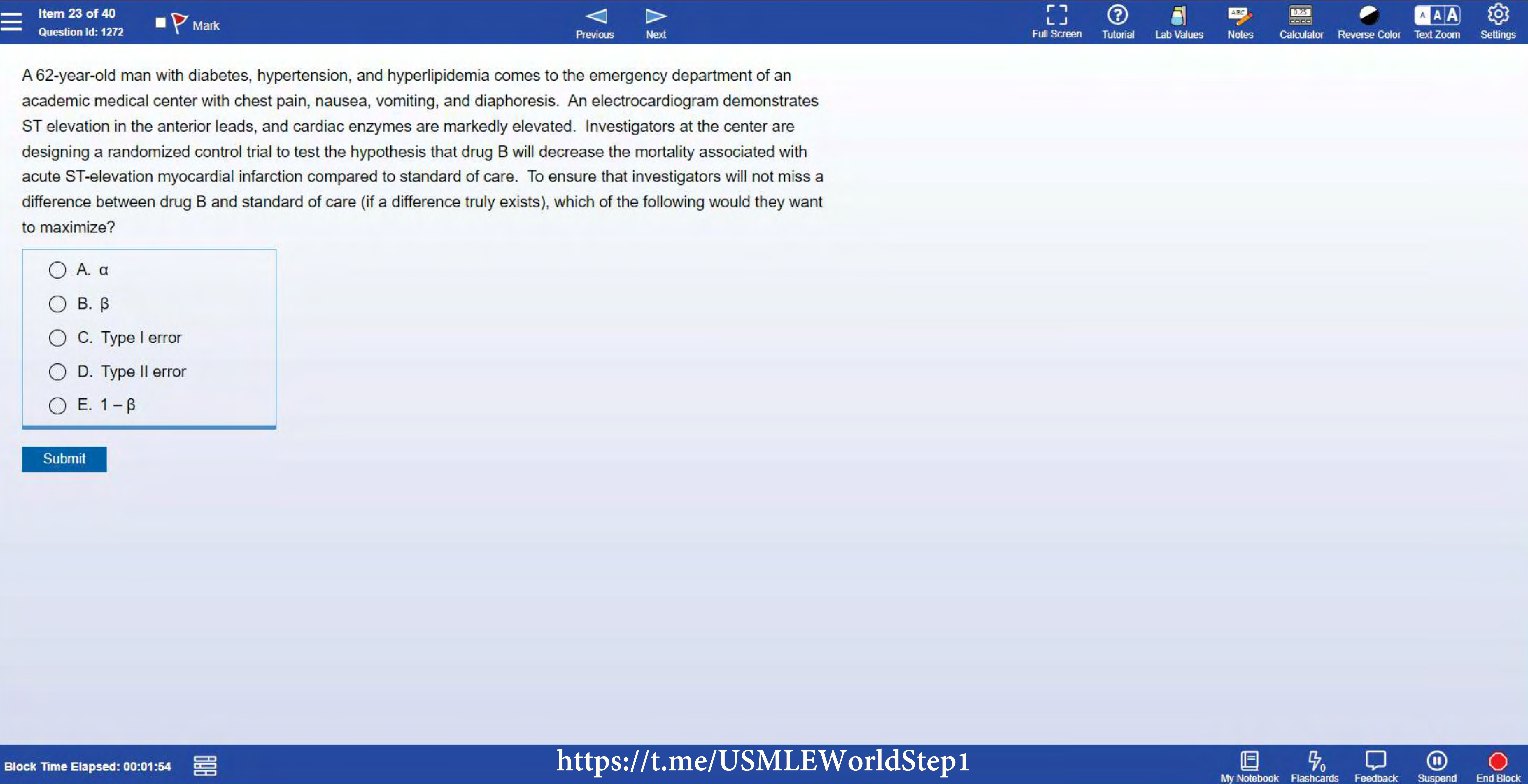
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A 62-year-old man with diabetes, hypertension, and hyperlipidemia comes to the emergency department of an academic medical center with chest pain, nausea, vomiting, and diaphoresis. An electrocardiogram demonstrates ST elevation in the anterior leads, and cardiac enzymes are markedly elevated. Investigators at the center are designing a randomized control trial to test the hypothesis that drug B will decrease the mortality associated with acute ST-elevation myocardial infarction compared to standard of care. To ensure that investigators will not miss a difference between drug B and standard of care (if a difference truly exists), which of the following would they want to maximize?

- ○ A. α
- ○ B. β
- ○ C. Type I error
- ○ D. Type II error
- ○ E. 1 – β

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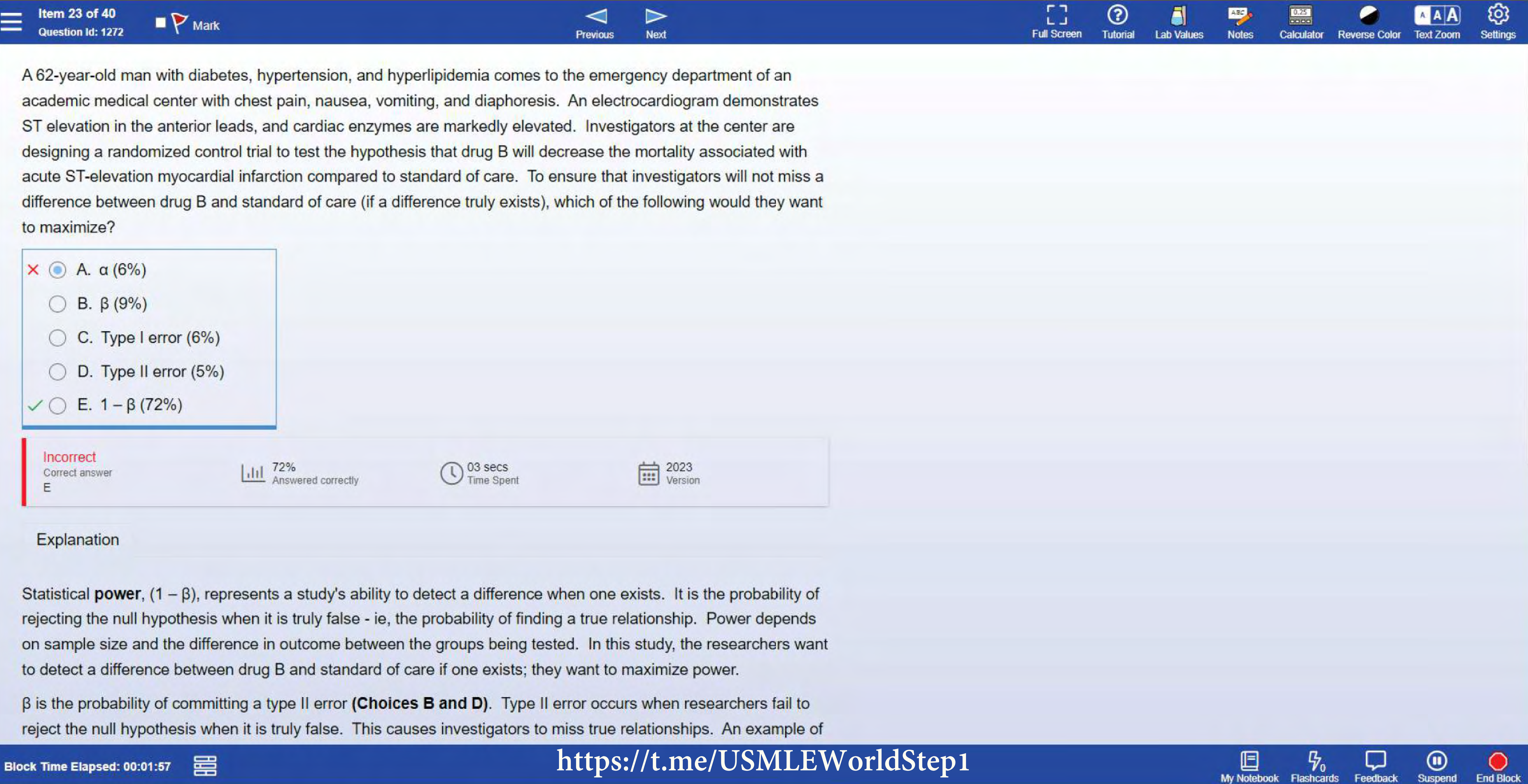
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✗ ● A. α (6%)
○ B. β (9%)
○ C. Type I error (6%)
○ D. Type II error (5%)
✓ ○ E. 1 – β (72%)

Incorrect
Correct answer
E

72%
Answered correctly

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Explanation

Statistical **power**, (1 – β), represents a study's ability to detect a difference when one exists. It is the probability of rejecting the null hypothesis when it is truly false - ie, the probability of finding a true relationship. Power depends on sample size and the difference in outcome between the groups being tested. In this study, the researchers want to detect a difference between drug B and standard of care if one exists; they want to maximize power.

β is the probability of committing a type II error **(Choices B and D)**. Type II error occurs when researchers fail to reject the null hypothesis when it is truly false. This causes investigators to miss true relationships. An example of

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Statistical **power**, (1 – β), represents a study's ability to detect a difference when one exists. It is the probability of rejecting the null hypothesis when it is truly false - ie, the probability of finding a true relationship. Power depends on sample size and the difference in outcome between the groups being tested. In this study, the researchers want to detect a difference between drug B and standard of care if one exists; they want to maximize power.

β is the probability of committing a type II error **(Choices B and D)**. Type II error occurs when researchers fail to reject the null hypothesis when it is truly false. This causes investigators to miss true relationships. An example of a type II error would be a study finding that aspirin does not affect platelet function when, in fact, it does. Therefore, if β is set at 0.2, the power will be (1 – β) = 80%; there will be an 80% chance of rejecting the null hypothesis when it is truly false.

(Choices A and C) Type I error occurs when researchers reject the null hypothesis when the null hypothesis is really true. That is, a study finds a statistically significant difference between 2 groups when one does not truly exist. An example would be if a study concluded that candy improves heart failure mortality when, in fact, it does not. α is the maximum probability of making a type I error that a researcher is willing to accept. Generally, α is compared to the p-value, the probability of observing a given result (or more extreme) due to chance alone assuming the null hypothesis is true (eg, if there is no real difference between the groups). The value of α is typically set at 0.05, meaning that researchers are willing to accept up to a 5% chance of making a type I error. In such a scenario, if $p < 0.05$, the result is said to be statistically significant.

Educational objective:

Power (1 – β) is the probability of rejecting a null hypothesis when it is truly false. It is typically set at 80% and depends on sample size and difference between outcomes.

Biostatistics	Biostatistics & Epidemiology	Power and sample size
Subject	System	Topic

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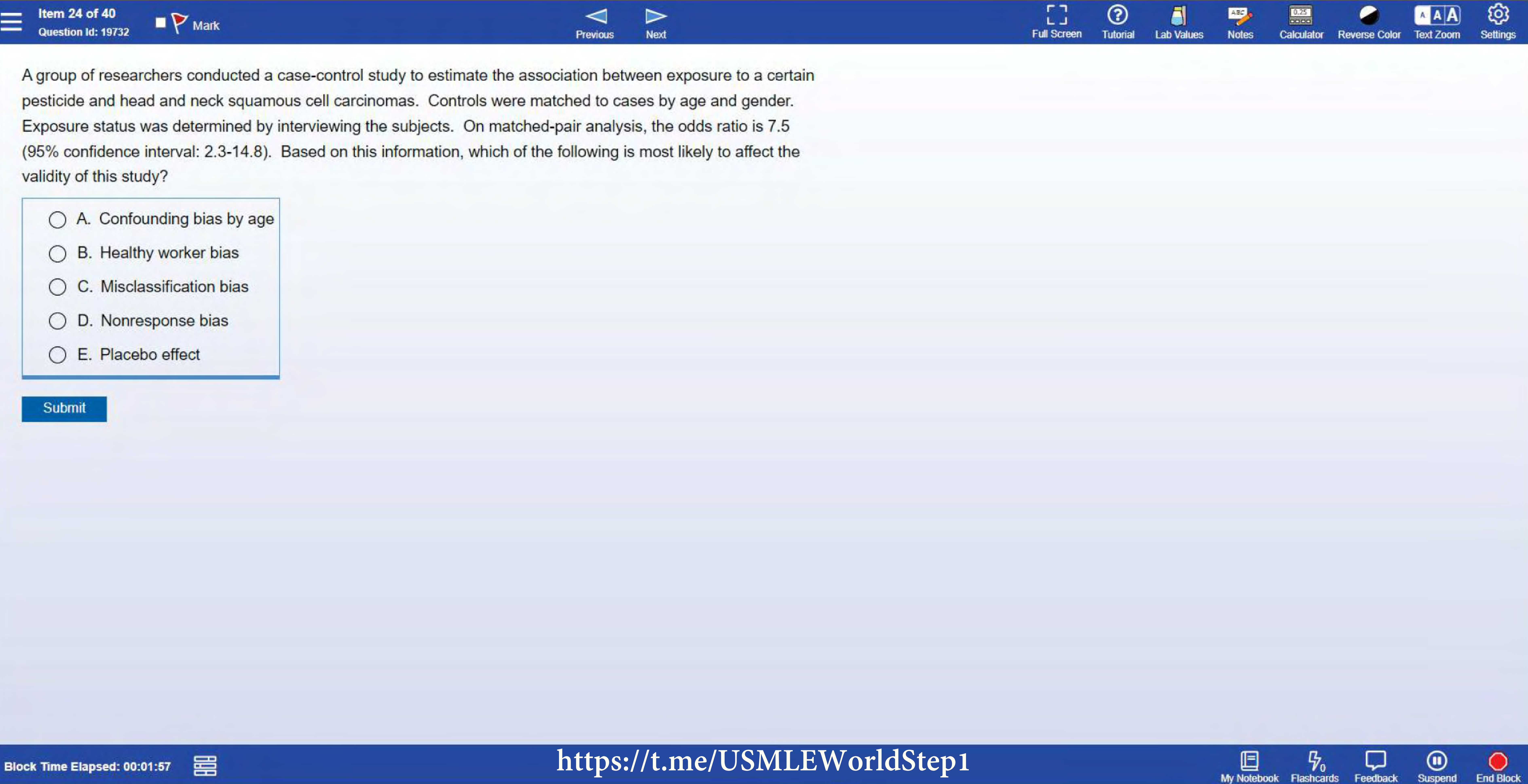
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A group of researchers conducted a case-control study to estimate the association between exposure to a certain pesticide and head and neck squamous cell carcinomas. Controls were matched to cases by age and gender. Exposure status was determined by interviewing the subjects. On matched-pair analysis, the odds ratio is 7.5 (95% confidence interval: 2.3-14.8). Based on this information, which of the following is most likely to affect the validity of this study?

- ○ A. Confounding bias by age
- ○ B. Healthy worker bias
- ○ C. Misclassification bias
- ○ D. Nonresponse bias
- ○ E. Placebo effect

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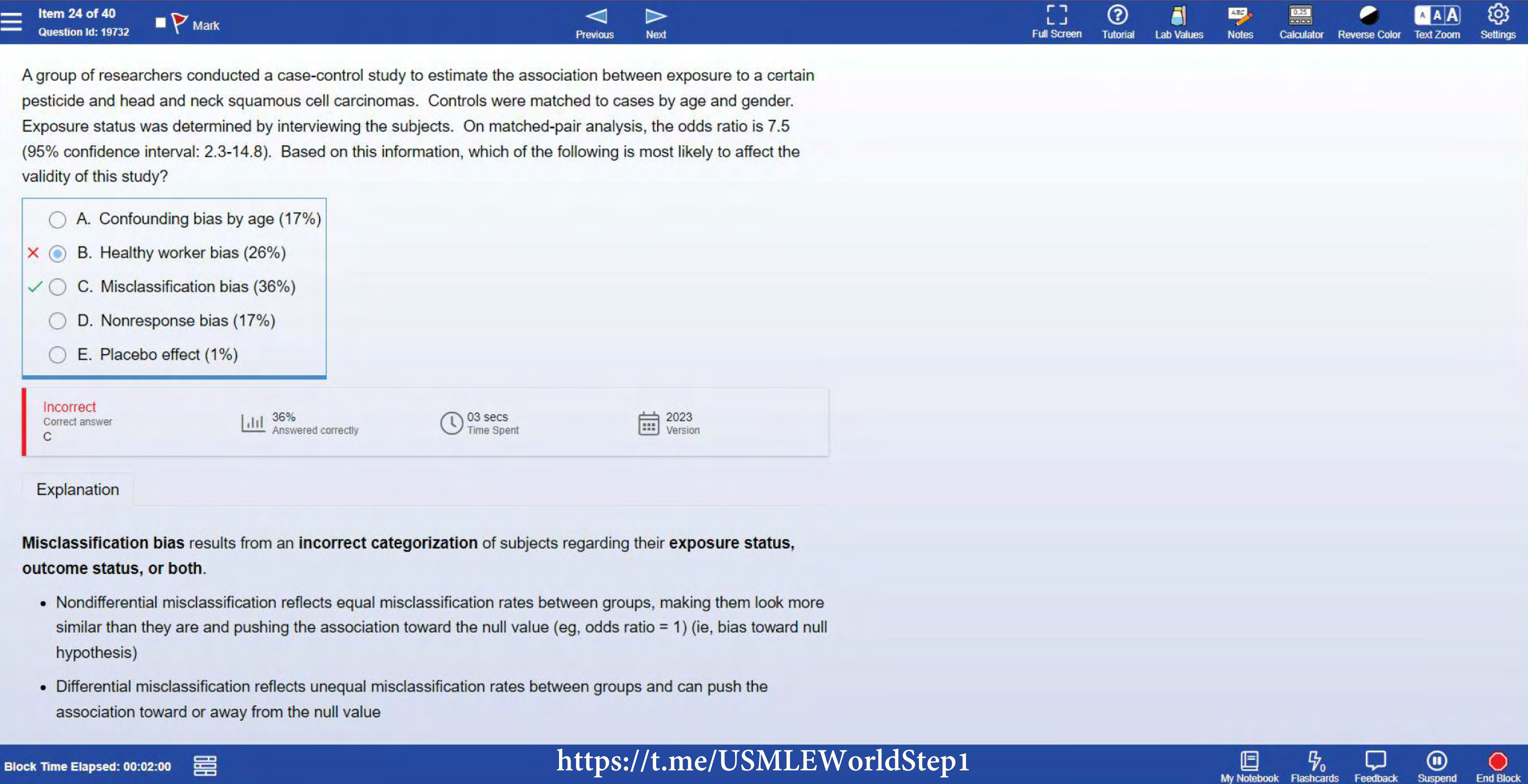
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A group of researchers conducted a case-control study to estimate the association between exposure to a certain pesticide and head and neck squamous cell carcinomas. Controls were matched to cases by age and gender. Exposure status was determined by interviewing the subjects. On matched-pair analysis, the odds ratio is 7.5 (95% confidence interval: 2.3-14.8). Based on this information, which of the following is most likely to affect the validity of this study?

○ A. Confounding bias by age (17%)
✗ ● B. Healthy worker bias (26%)
✓ ○ C. Misclassification bias (36%)
○ D. Nonresponse bias (17%)
○ E. Placebo effect (1%)

Incorrect
Correct answer
C

36%
Answered correctly

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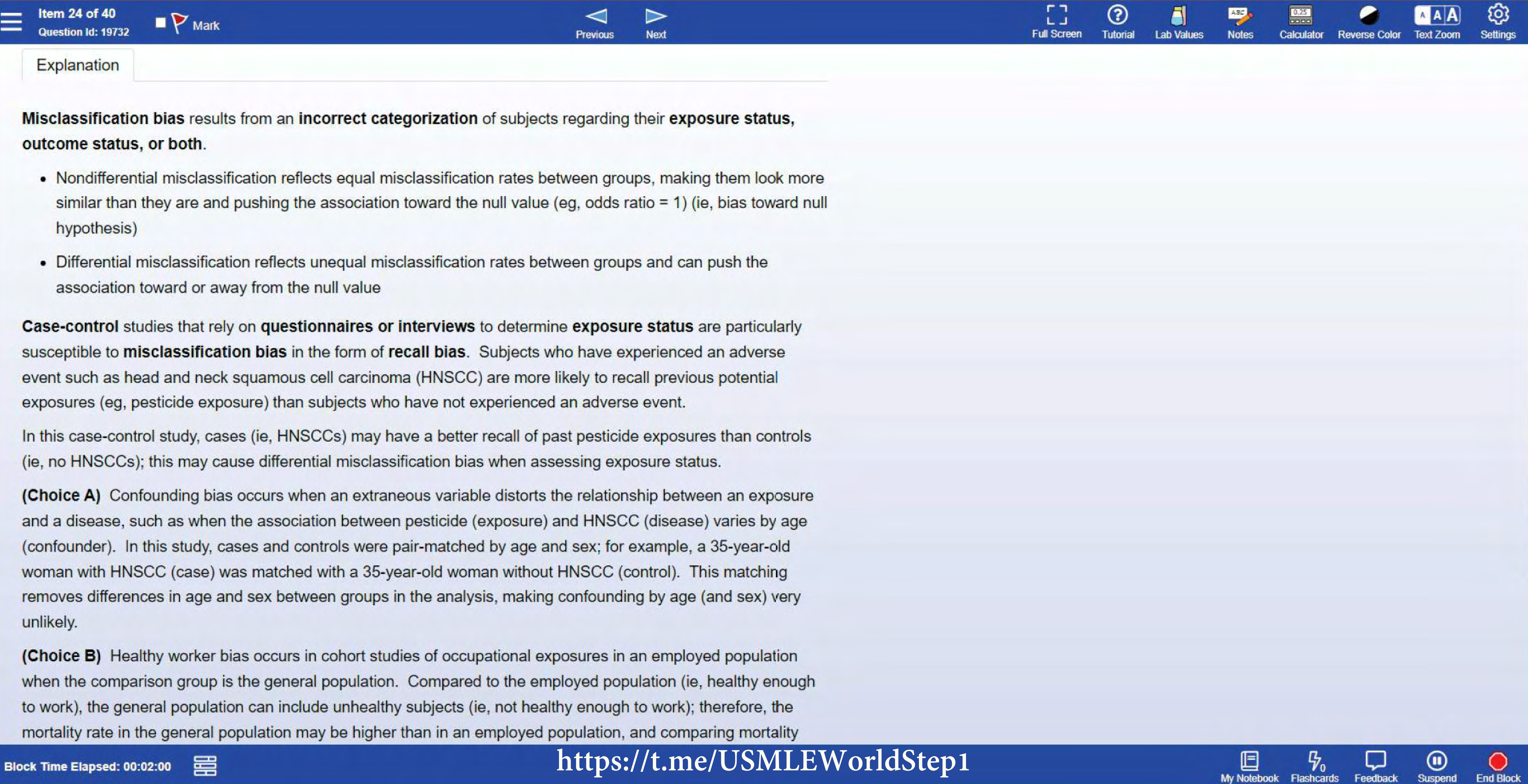
Version

Explanation

Misclassification bias results from an **incorrect categorization** of subjects regarding their **exposure status, outcome status, or both**.

- Nondifferential misclassification reflects equal misclassification rates between groups, making them look more similar than they are and pushing the association toward the null value (eg, odds ratio = 1) (ie, bias toward null hypothesis)
- Differential misclassification reflects unequal misclassification rates between groups and can push the association toward or away from the null value



Misclassification bias results from an **incorrect categorization** of subjects regarding their **exposure status, outcome status, or both**.

- Nondifferential misclassification reflects equal misclassification rates between groups, making them look more similar than they are and pushing the association toward the null value (eg, odds ratio = 1) (ie, bias toward null hypothesis)
- Differential misclassification reflects unequal misclassification rates between groups and can push the association toward or away from the null value

Case-control studies that rely on **questionnaires or interviews** to determine **exposure status** are particularly susceptible to **misclassification bias** in the form of **recall bias**. Subjects who have experienced an adverse event such as head and neck squamous cell carcinoma (HNSCC) are more likely to recall previous potential exposures (eg, pesticide exposure) than subjects who have not experienced an adverse event.

In this case-control study, cases (ie, HNSCCs) may have a better recall of past pesticide exposures than controls (ie, no HNSCCs); this may cause differential misclassification bias when assessing exposure status.

(Choice A) Confounding bias occurs when an extraneous variable distorts the relationship between an exposure and a disease, such as when the association between pesticide (exposure) and HNSCC (disease) varies by age (confounder). In this study, cases and controls were pair-matched by age and sex; for example, a 35-year-old woman with HNSCC (case) was matched with a 35-year-old woman without HNSCC (control). This matching removes differences in age and sex between groups in the analysis, making confounding by age (and sex) very unlikely.

(Choice B) Healthy worker bias occurs in cohort studies of occupational exposures in an employed population when the comparison group is the general population. Compared to the employed population (ie, healthy enough to work), the general population can include unhealthy subjects (ie, not healthy enough to work); therefore, the mortality rate in the general population may be higher than in an employed population, and comparing mortality

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exposures (eg, pesticide exposure) than subjects who have not experienced an adverse event.

In this case-control study, cases (ie, HNSCCs) may have a better recall of past pesticide exposures than controls (ie, no HNSCCs); this may cause differential misclassification bias when assessing exposure status.

(Choice A) Confounding bias occurs when an extraneous variable distorts the relationship between an exposure and a disease, such as when the association between pesticide (exposure) and HNSCC (disease) varies by age (confounder). In this study, cases and controls were pair-matched by age and sex; for example, a 35-year-old woman with HNSCC (case) was matched with a 35-year-old woman without HNSCC (control). This matching removes differences in age and sex between groups in the analysis, making confounding by age (and sex) very unlikely.

(Choice B) Healthy worker bias occurs in cohort studies of occupational exposures in an employed population when the comparison group is the general population. Compared to the employed population (ie, healthy enough to work), the general population can include unhealthy subjects (ie, not healthy enough to work); therefore, the mortality rate in the general population may be higher than in an employed population, and comparing mortality rates between these 2 cohorts is biased.

(Choice D) Nonresponse bias occurs when respondents differ from nonrespondents in such meaningful ways that threaten the generalizability of study results. It most often occurs when data is collected by mailed surveys or questionnaires; in this study, patients were directly interviewed, making nonresponse bias less likely.

(Choice E) The placebo effect occurs in randomized controlled trials and refers to patients' expectations affecting an outcome. In this case, the study is a case-control.

Educational objective:

Misclassification bias is an incorrect categorization of subjects regarding their exposure, outcome status, or both. In case-control studies, recall bias usually leads to misclassification of the exposure status.

Biostatistics	Biostatistics & Epidemiology	Bias
Subject	System	Topic

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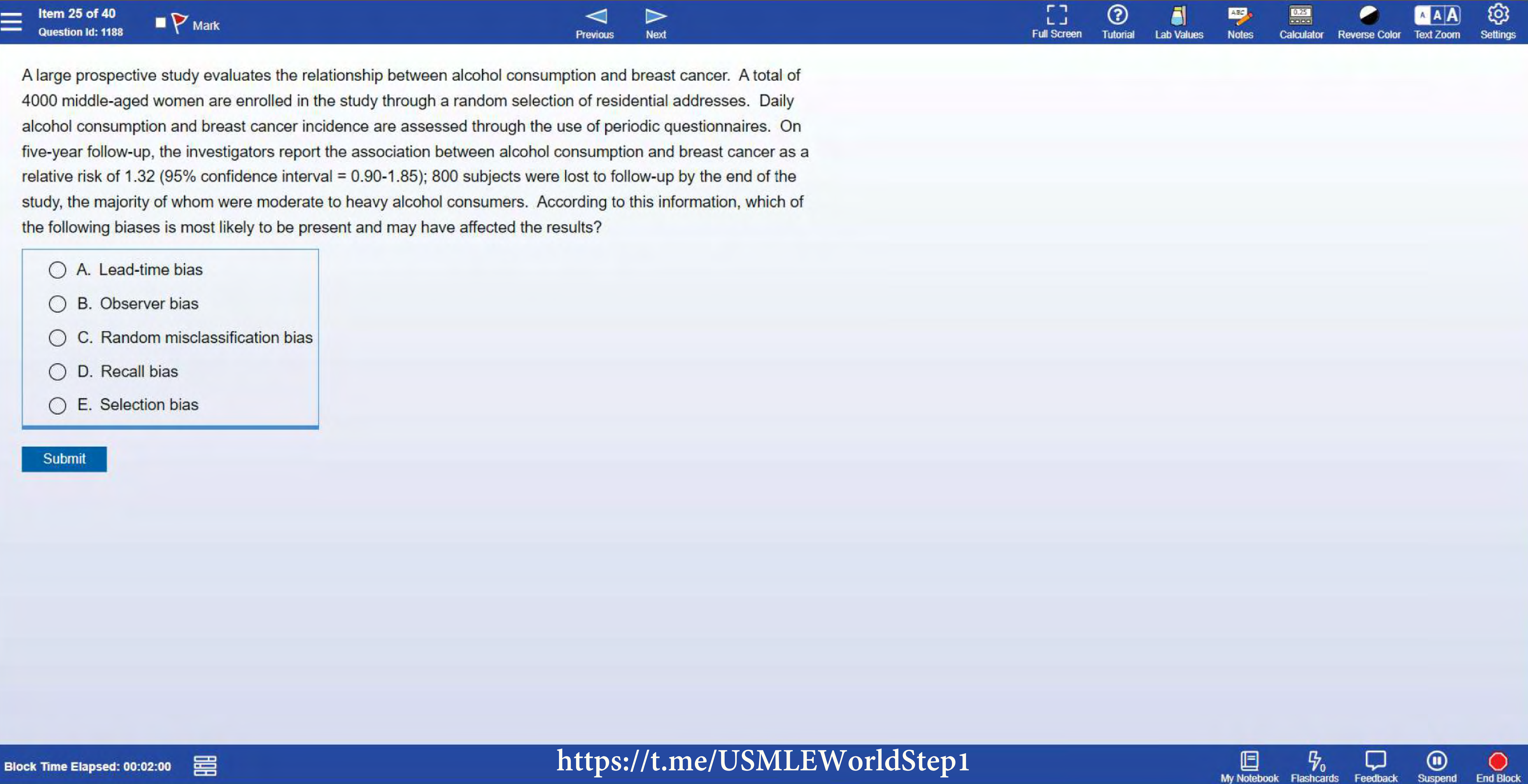
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A large prospective study evaluates the relationship between alcohol consumption and breast cancer. A total of 4000 middle-aged women are enrolled in the study through a random selection of residential addresses. Daily alcohol consumption and breast cancer incidence are assessed through the use of periodic questionnaires. On five-year follow-up, the investigators report the association between alcohol consumption and breast cancer as a relative risk of 1.32 (95% confidence interval = 0.90-1.85); 800 subjects were lost to follow-up by the end of the study, the majority of whom were moderate to heavy alcohol consumers. According to this information, which of the following biases is most likely to be present and may have affected the results?

○ A. Lead-time bias
○ B. Observer bias
○ C. Random misclassification bias
○ D. Recall bias
○ E. Selection bias

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- ✗ ● A. Lead-time bias (13%)
- ○ B. Observer bias (6%)
- ○ C. Random misclassification bias (11%)
- ○ D. Recall bias (11%)
- ✓ ○ E. Selection bias (56%)

Incorrect
Correct answer
E

56%
Answered correctly

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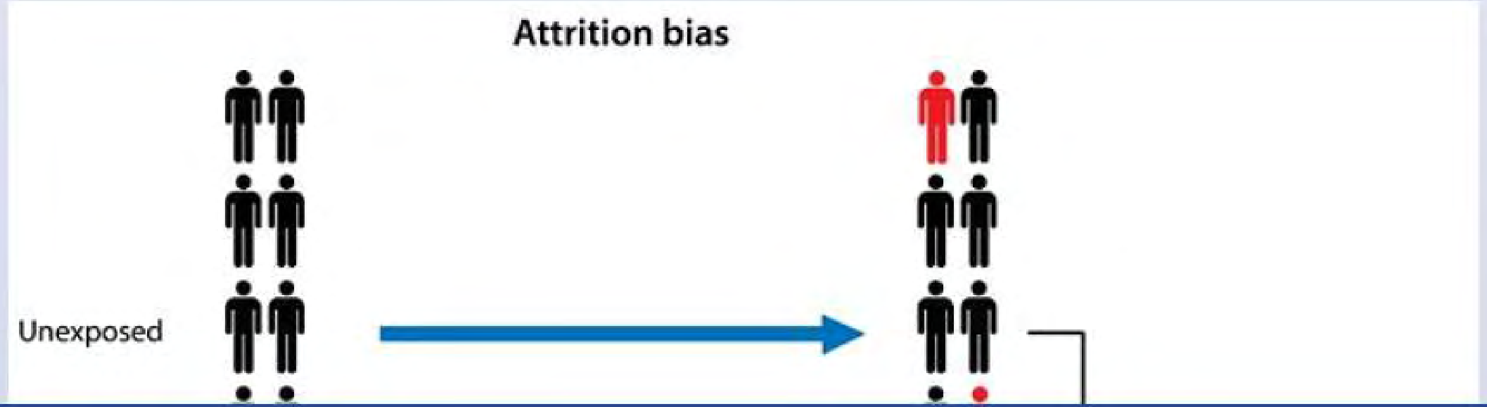
Explanation



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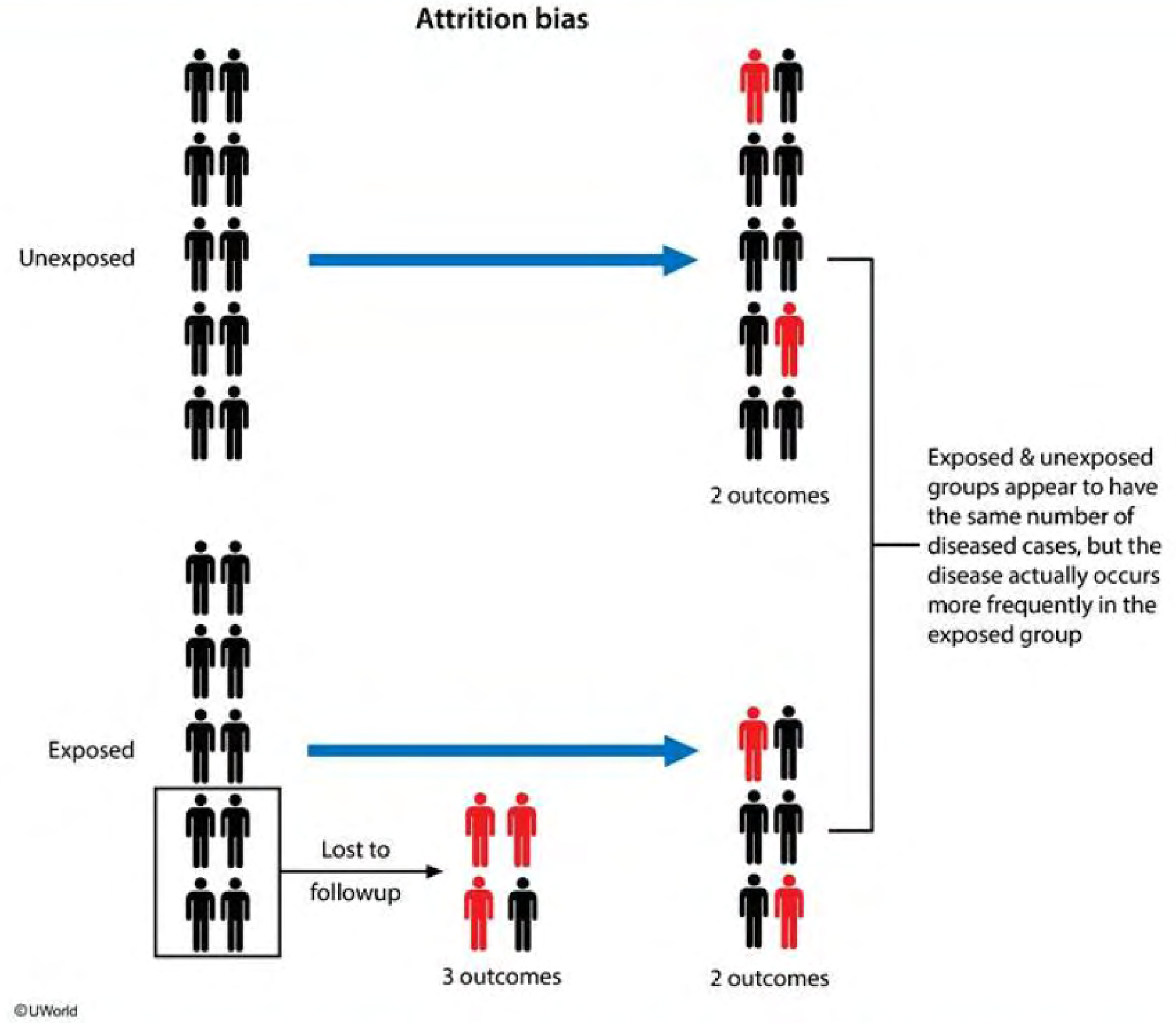
Attrition bias
Unexposed
2 outcomes
Exposed
Lost to followup
3 outcomes
2 outcomes
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Exposed & unexposed groups appear to have the same number of diseased cases, but the disease actually occurs more frequently in the exposed group

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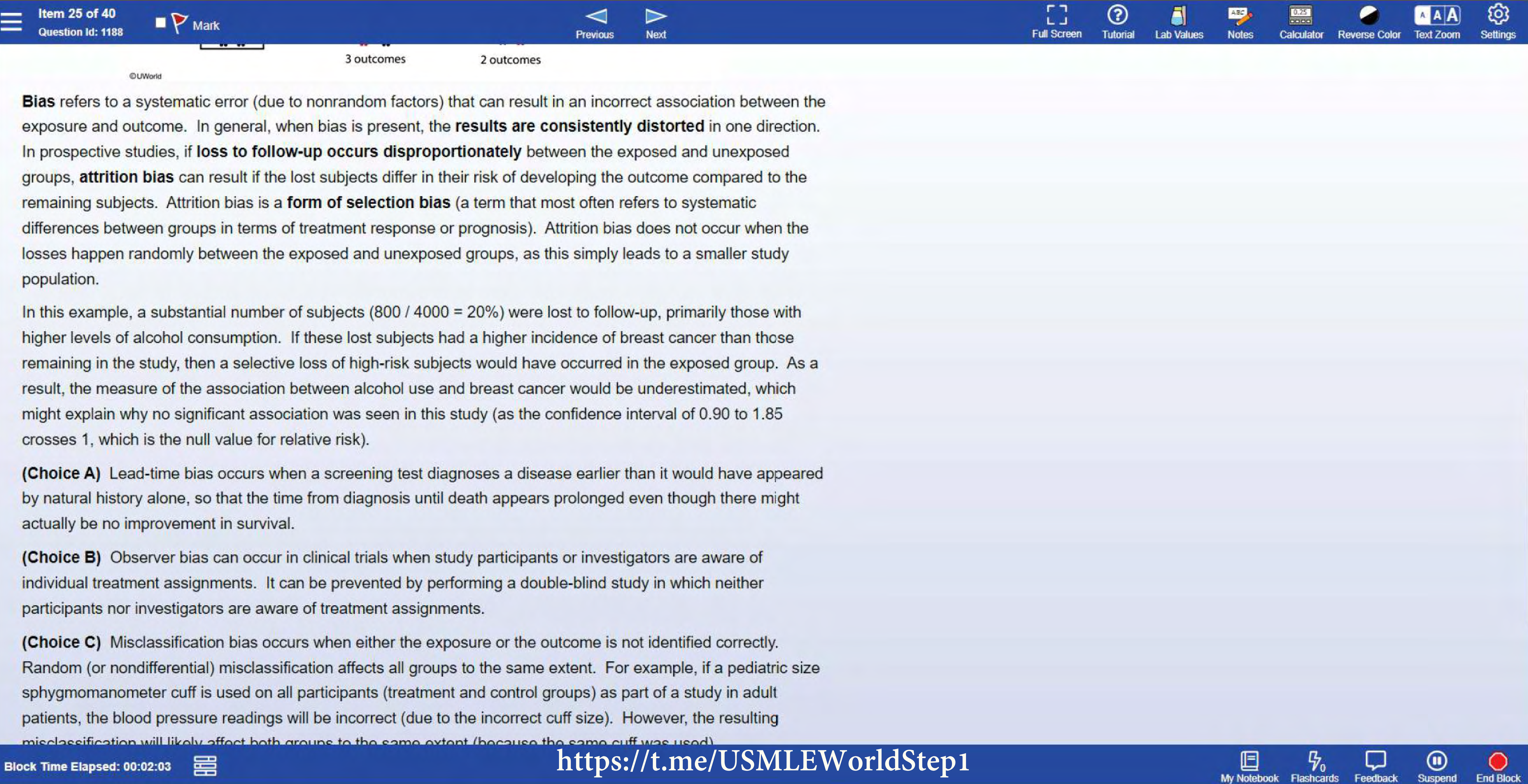
Unexposed



Bias refers to a systematic error (due to nonrandom factors) that can result in an incorrect association between the exposure and outcome. In general, when bias is present, the **results are consistently distorted** in one direction. In prospective studies, if **loss to follow-up occurs disproportionately** between the exposed and unexposed groups, **attrition bias** can result if the lost subjects differ in their risk of developing the outcome compared to the remaining subjects. Attrition bias is a **form of selection bias** (a term that most often refers to systematic differences between groups in terms of treatment response or prognosis). Attrition bias does not occur when the losses happen randomly between the exposed and unexposed groups, as this simply leads to a smaller study population.

In this example, a substantial number of subjects (800 / 4000 = 20%) were lost to follow-up, primarily those with higher levels of alcohol consumption. If these lost subjects had a higher incidence of breast cancer than those remaining in the study, then a selective loss of high-risk subjects would have occurred in the exposed group. As a result, the measure of the association between alcohol use and breast cancer would be underestimated, which might explain why no significant association was seen in this study (as the confidence interval of 0.90 to 1.85 crosses 1, which is the null value for relative risk).

(Choice A) Lead-time bias occurs when a screening test diagnoses a disease earlier than it would have appeared by natural history alone, so that the time from diagnosis until death appears prolonged even though there might actually be no improvement in survival.

(Choice B) Observer bias can occur in clinical trials when study participants or investigators are aware of individual treatment assignments. It can be prevented by performing a double-blind study in which neither participants nor investigators are aware of treatment assignments.

(Choice C) Misclassification bias occurs when either the exposure or the outcome is not identified correctly. Random (or nondifferential) misclassification affects all groups to the same extent. For example, if a pediatric size sphygmomanometer cuff is used on all participants (treatment and control groups) as part of a study in adult patients, the blood pressure readings will be incorrect (due to the incorrect cuff size). However, the resulting misclassification will likely affect both groups to the same extent (because the same cuff was used).

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result, the measure of the association between alcohol use and breast cancer would be underestimated, which might explain why no significant association was seen in this study (as the confidence interval of 0.90 to 1.85 crosses 1, which is the null value for relative risk).

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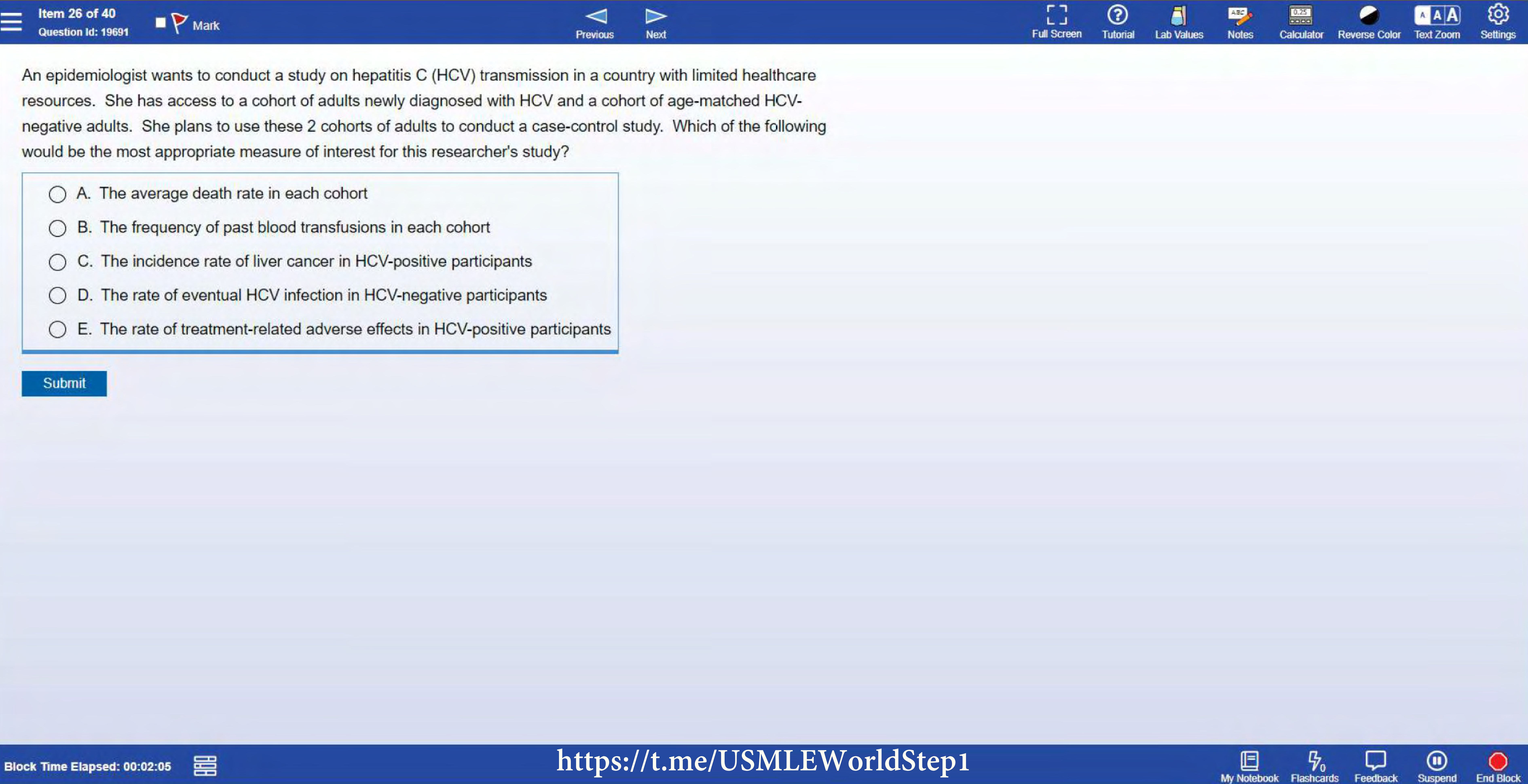
(Choice D) Recall bias results from the inaccurate recall of past exposure status. It is a potential problem for retrospective studies such as case-control studies, particularly when questionnaires are used to inquire about distant past exposure. However, in this prospective study, exposure status is determined through periodic questionnaires assessing daily alcohol consumption (without inquiring about distant past exposure). In such a scenario, recall bias is less likely to affect results.

Educational objective:

In prospective studies, disproportionate loss to follow-up between the exposed and unexposed groups creates the potential for attrition bias, which is a form of selection bias. As a result, investigators generally try to achieve high patient follow-up rates in prospective studies.

Biostatistics	Biostatistics & Epidemiology	Confounding, effect modification, bias, errors
Subject	System	Topic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An epidemiologist wants to conduct a study on hepatitis C (HCV) transmission in a country with limited healthcare resources. She has access to a cohort of adults newly diagnosed with HCV and a cohort of age-matched HCV-negative adults. She plans to use these 2 cohorts of adults to conduct a case-control study. Which of the following would be the most appropriate measure of interest for this researcher's study?

○ A. The average death rate in each cohort
○ B. The frequency of past blood transfusions in each cohort
○ C. The incidence rate of liver cancer in HCV-positive participants
○ D. The rate of eventual HCV infection in HCV-negative participants
○ E. The rate of treatment-related adverse effects in HCV-positive participants

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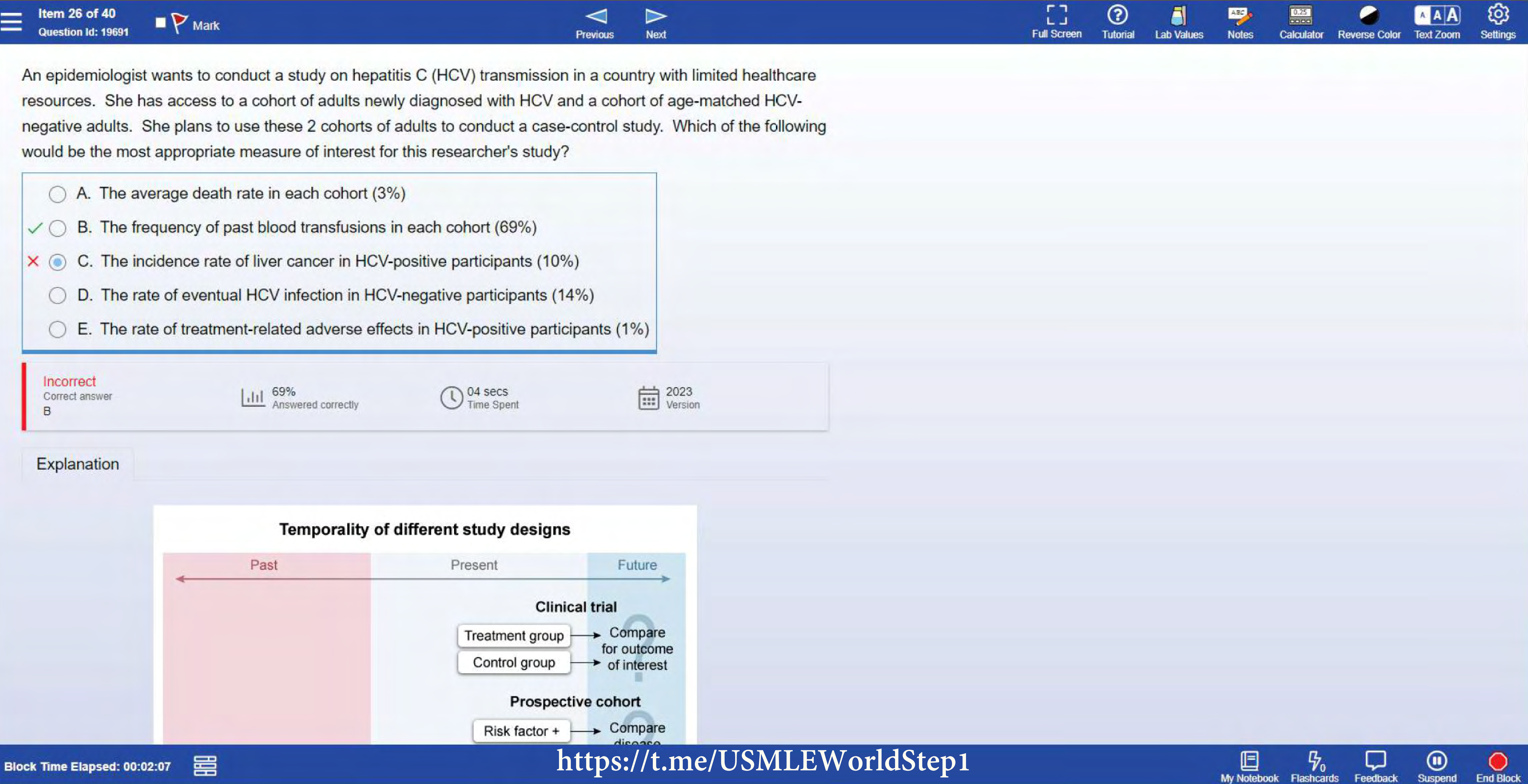

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- ○ A. The average death rate in each cohort (3%)
- ✓ ○ B. The frequency of past blood transfusions in each cohort (69%)
- ✗ ● C. The incidence rate of liver cancer in HCV-positive participants (10%)
- ○ D. The rate of eventual HCV infection in HCV-negative participants (14%)
- ○ E. The rate of treatment-related adverse effects in HCV-positive participants (1%)

Incorrect
Correct answer
B

69%
Answered correctly

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Explanation

Temporality of different study designs

Past
Present
Future
Clinical trial
Treatment group
Control group
Compare for outcome of interest
Prospective cohort
Risk factor +
Compare disease

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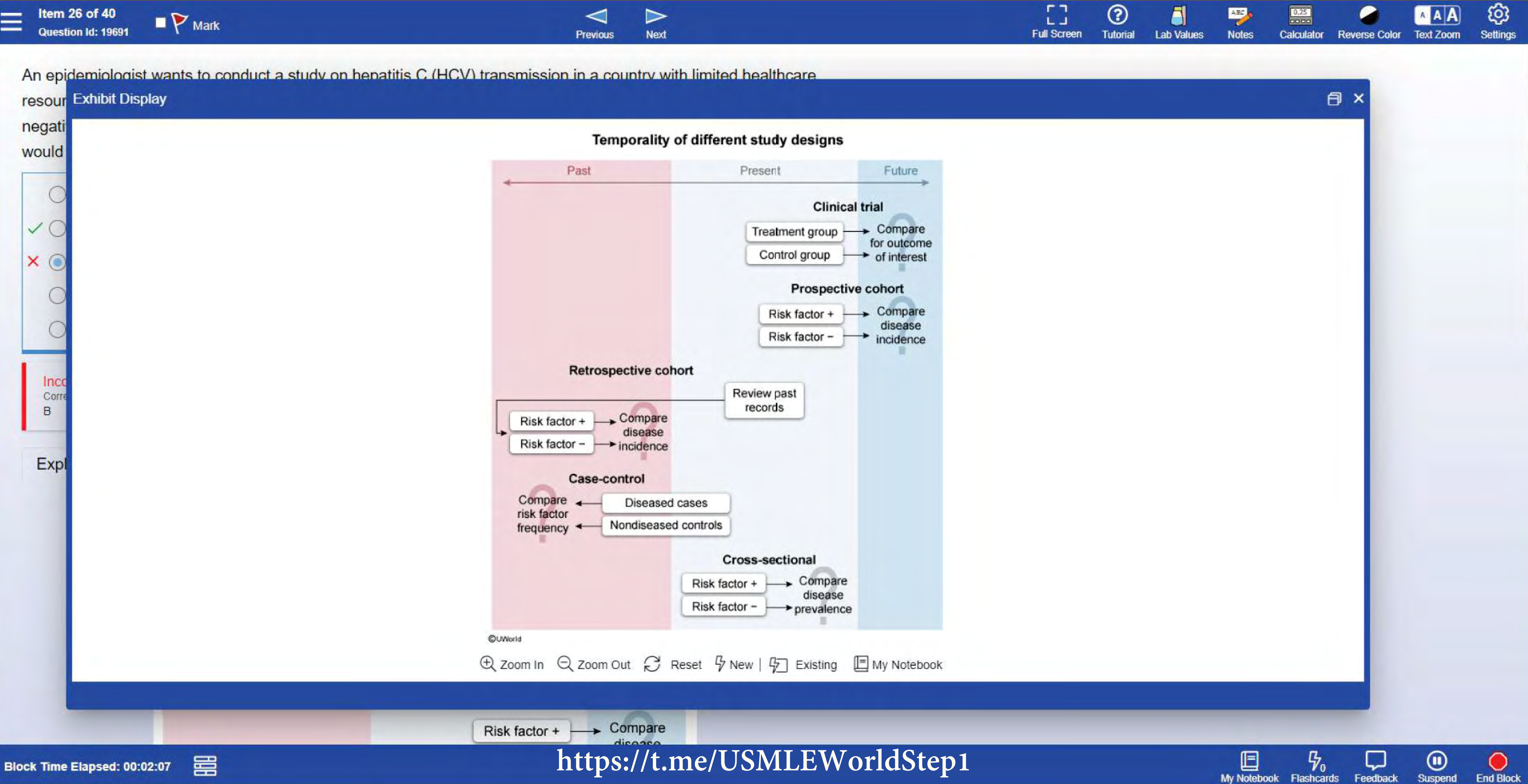
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Temporality of different study designs

Past
Present
Future
Clinical trial
Treatment group
Control group
Compare for outcome of interest
Prospective cohort
Risk factor +
Risk factor –
Compare disease incidence
Retrospective cohort
Review past records
Risk factor +
Risk factor –
Compare disease incidence
Case-control
Compare risk factor frequency
Diseased cases
Nondiseased controls
Cross-sectional
Risk factor +
Risk factor –
Compare disease prevalence

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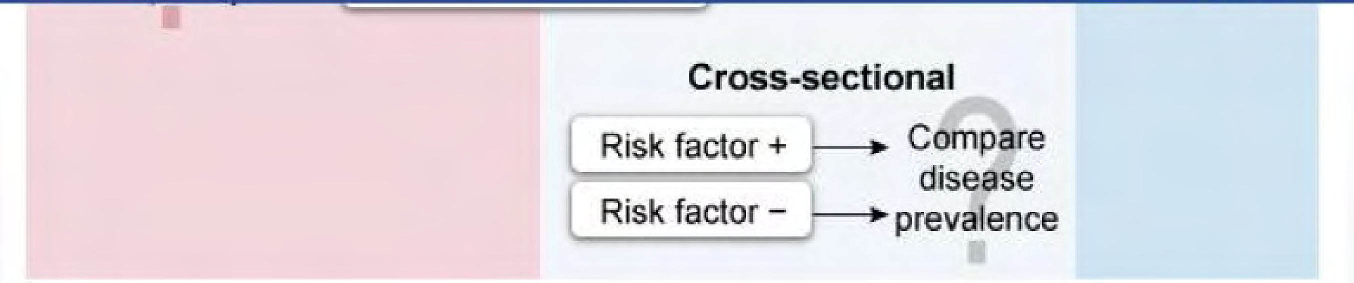

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A **case-control** study is an observational study design in which potential participants are initially identified as **cases** or **controls** according to their **disease status** (ie, have or do not have the disease of interest).

In the study described above, a cohort of adults newly diagnosed with hepatitis C (HCV) represents the cases, and a cohort of HCV-negative adults represents the controls. Note that "cohort" in this case refers to a group of individuals with similar characteristics (eg, HCV-positivity), not to a "cohort study," in which a group of individuals are followed over time.

Once cases and controls are identified, the **frequency** of past exposure to ≥1 **risk factors** of interest is compared between cases and controls to estimate the **association** between the risk factors and the outcomes. Therefore, an **appropriate measure** for the proposed study would be any event that **preceded HCV infection**. Among the given choices, a history of **past blood transfusions** precedes HCV infection.

Because of the retrospective nature of a case-control study, this study design is not able to compare the frequency (ie, incidence, risk, rate) of any event that occurs after a disease has been diagnosed (ie, prospective outcomes). Prospective outcomes are reasonable in cohort studies and experimental designs **(Choices A, C, D, and E)**.

Educational objective:

In a case-control study, potential participants are initially identified as cases or controls according to their disease status. The frequency of past exposure to ≥1 risk factors of interest is then compared between cases and controls to estimate the association between the risk factors and the outcomes.

Biostatistics	Biostatistics & Epidemiology	Case control studies
Subject	System	Topic

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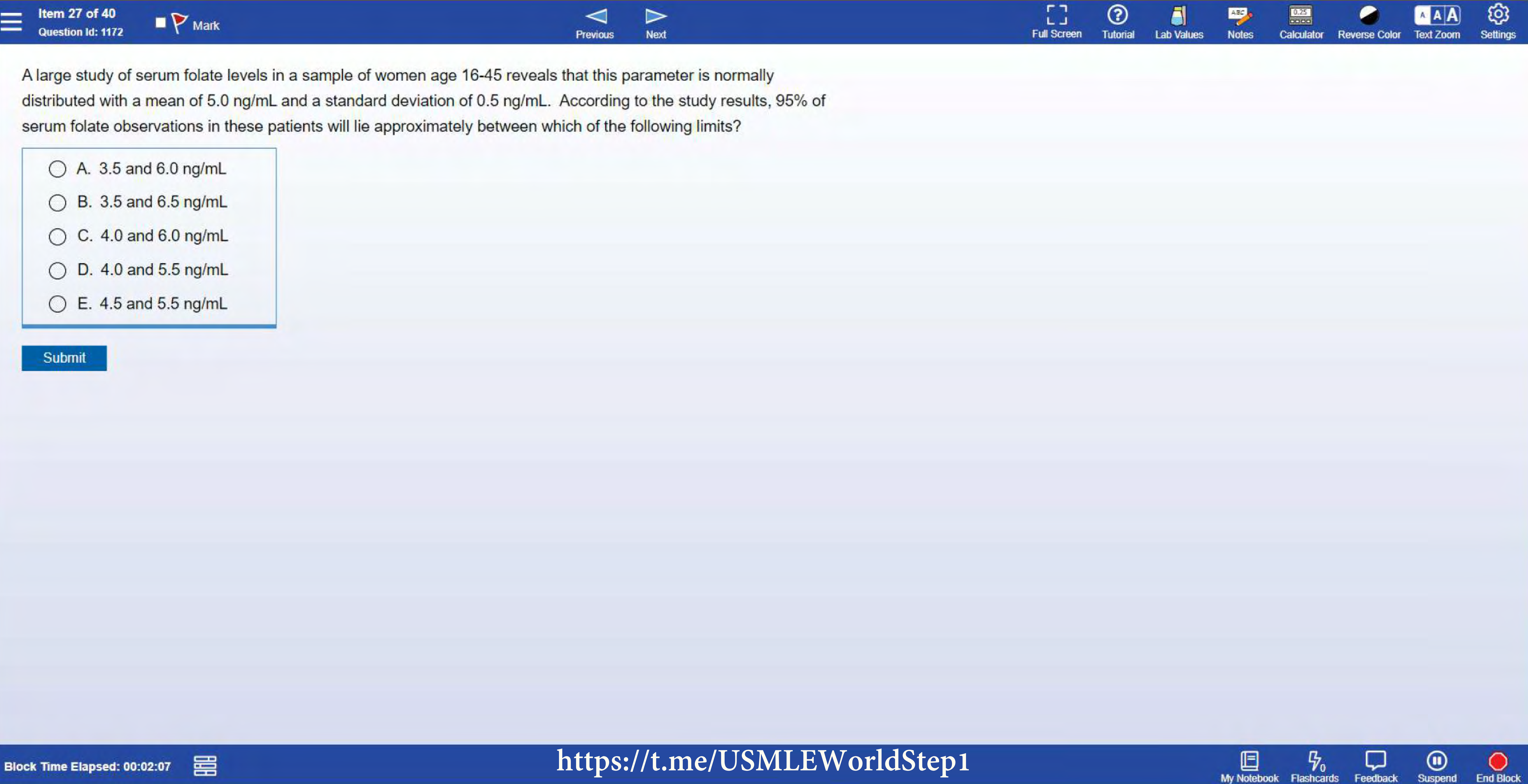
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A large study of serum folate levels in a sample of women age 16-45 reveals that this parameter is normally distributed with a mean of 5.0 ng/mL and a standard deviation of 0.5 ng/mL. According to the study results, 95% of serum folate observations in these patients will lie approximately between which of the following limits?

○ A. 3.5 and 6.0 ng/mL
○ B. 3.5 and 6.5 ng/mL
○ C. 4.0 and 6.0 ng/mL
○ D. 4.0 and 5.5 ng/mL
○ E. 4.5 and 5.5 ng/mL

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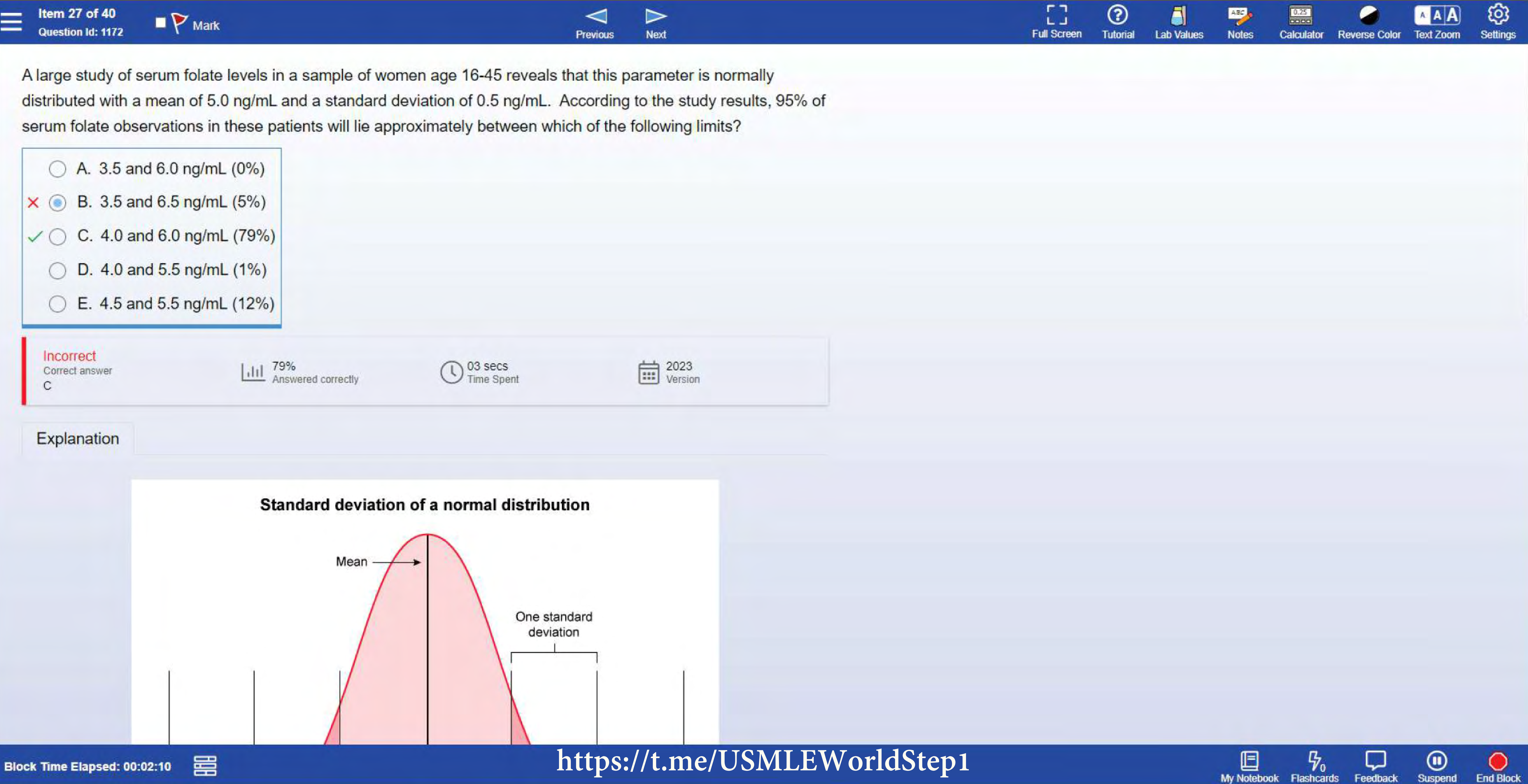
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○ A. 3.5 and 6.0 ng/mL (0%)
✗ ● B. 3.5 and 6.5 ng/mL (5%)
✓ ○ C. 4.0 and 6.0 ng/mL (79%)
○ D. 4.0 and 5.5 ng/mL (1%)
○ E. 4.5 and 5.5 ng/mL (12%)

Incorrect
Correct answer
C

79%
Answered correctly

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Explanation

Standard deviation of a normal distribution

Mean
One standard deviation

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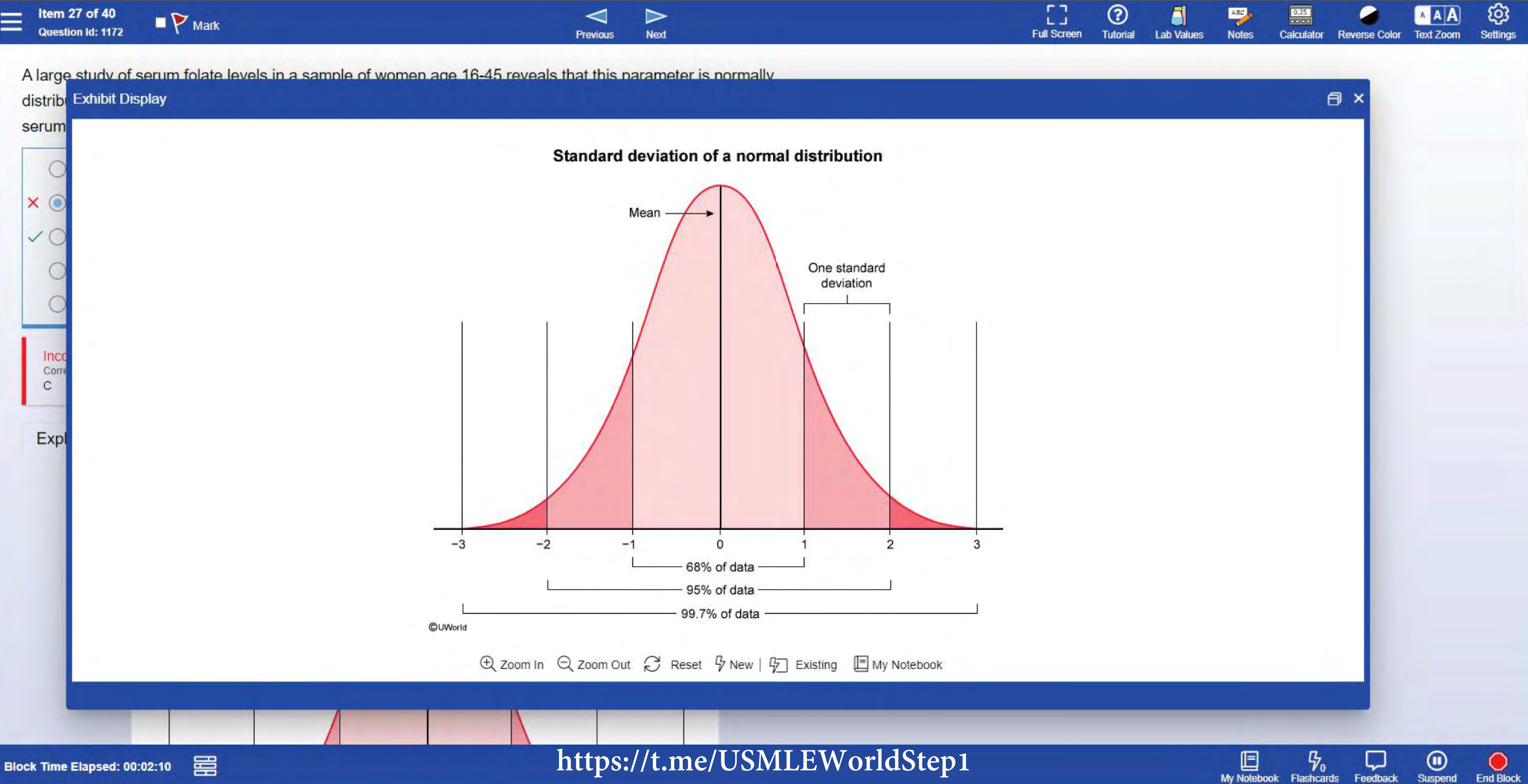
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A large study of serum folate levels in a sample of women age 16-45 reveals that this parameter is normally

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Standard deviation of a normal distribution

Mean
One standard deviation
−3
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68% of data
95% of data
99.7% of data
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A **normal (Gaussian) distribution** is defined as a symmetrical, bell-shaped distribution curve. One of the most important attributes of the normal distribution is the **"68/95/99 rule,"** which states that 68% of all observations lie within 1 standard deviation (SD) of the mean, 95% within 2 SDs of the mean, and 99.7% within 3 SDs of the mean. The SD is a measure of dispersion or variance (how far the measurements are from one another). In this example, the mean folate level is 5.0 ng/mL with a SD of 0.5 ng/mL. Therefore:

- 4.5-5.5 ng/mL is the range within +/- 1 SD of 5.0 ng/mL (given that 5.0 – 1*0.5 = 4.5 ng/mL and 5 + 1*0.5 = 5.5 ng/mL);
- 4.0-6.0 ng/mL is the range within +/- 2 SDs of 5.0 ng/mL (given that 5.0 – 2*0.5 = 4.0 ng/mL and 5.0 + 2*0.5 = 6.0 ng/mL)
- 3.5-6.5 ng/mL is the range within +/- 3 SDs of 5.0 ng/mL (given that 5.0 – 3*0.5 = 3.5 ng/mL and 5.0 + 3*0.5 = 6.5 ng/mL)

Based on the 68/95/99 rule, approximately 95% of observations lie within 2 SDs of the mean, so between 4.0 and 6.0 ng/mL in this case. These are helpful approximations; to be more precise, 95% of the observations lie within 1.96 SDs of the mean and 95.45% of the observations lie within 2 SDs of the mean.

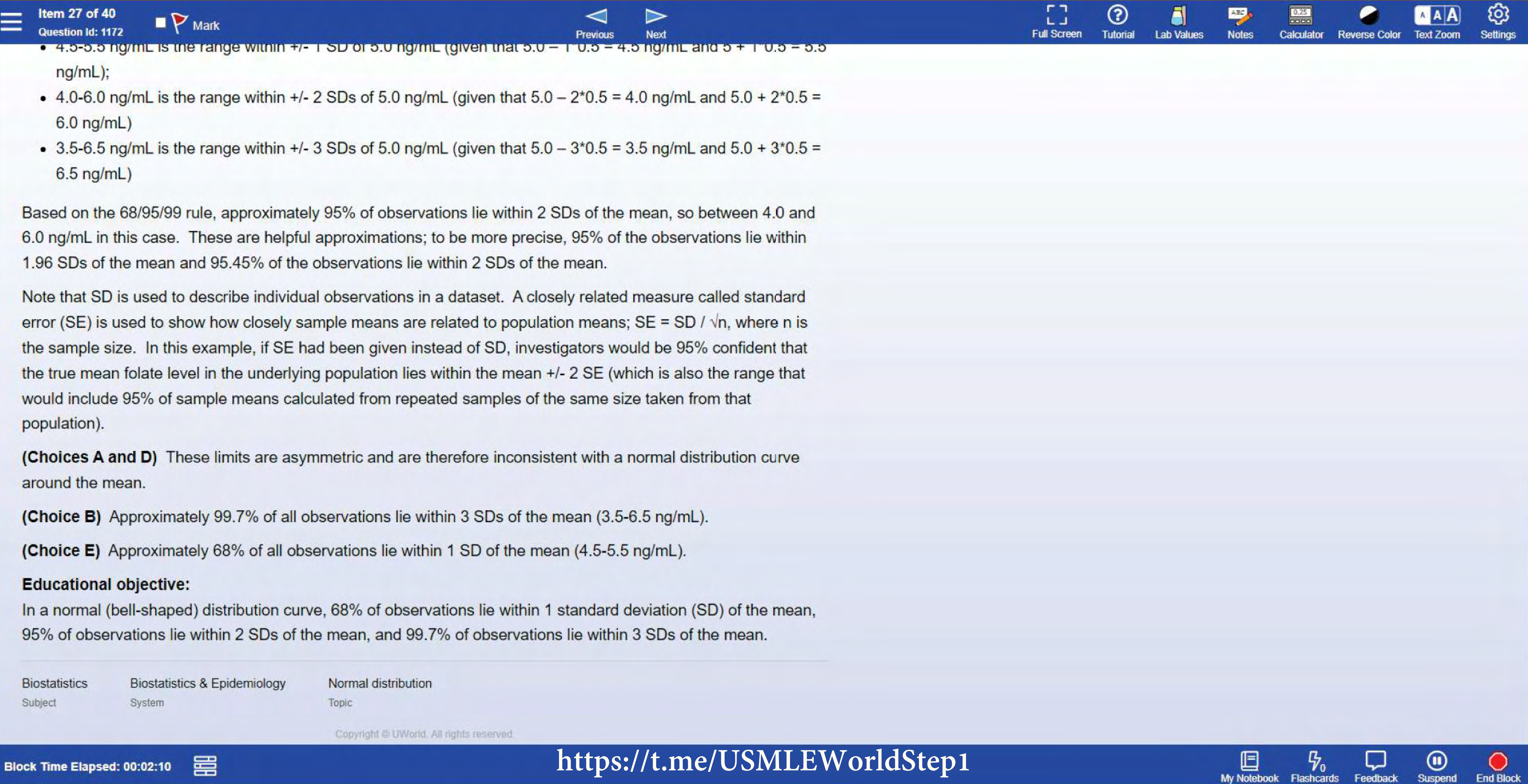
Note that SD is used to describe individual observations in a dataset. A closely related measure called standard error (SE) is used to show how closely sample means are related to population means; $SE = SD / \sqrt{n}$, where n is the sample size. In this example, if SE had been given instead of SD, investigators would be 95% confident that the true mean folate level in the underlying population lies within the mean +/- 2 SE (which is also the range that would include 95% of sample means calculated from repeated samples of the same size taken from that population).

(Choices A and D) These limits are asymmetric and are therefore inconsistent with a normal distribution curve around the mean.

(Choice B) Approximately 99.7% of all observations lie within 3 SDs of the mean (3.5-6.5 ng/mL).

(Choice E) Approximately 68% of all observations lie within 1 SD of the mean (4.5-5.5 ng/mL).

Educational objective: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- 4.5-5.5 ng/mL is the range within +/- 1 SD of 5.0 ng/mL (given that 5.0 – 1*0.5 = 4.5 ng/mL and 5 + 1*0.5 = 5.5 ng/mL);
- 4.0-6.0 ng/mL is the range within +/- 2 SDs of 5.0 ng/mL (given that 5.0 – 2*0.5 = 4.0 ng/mL and 5.0 + 2*0.5 = 6.0 ng/mL)
- 3.5-6.5 ng/mL is the range within +/- 3 SDs of 5.0 ng/mL (given that 5.0 – 3*0.5 = 3.5 ng/mL and 5.0 + 3*0.5 = 6.5 ng/mL)

Based on the 68/95/99 rule, approximately 95% of observations lie within 2 SDs of the mean, so between 4.0 and 6.0 ng/mL in this case. These are helpful approximations; to be more precise, 95% of the observations lie within 1.96 SDs of the mean and 95.45% of the observations lie within 2 SDs of the mean.

Note that SD is used to describe individual observations in a dataset. A closely related measure called standard error (SE) is used to show how closely sample means are related to population means; SE = SD / √n, where n is the sample size. In this example, if SE had been given instead of SD, investigators would be 95% confident that the true mean folate level in the underlying population lies within the mean +/- 2 SE (which is also the range that would include 95% of sample means calculated from repeated samples of the same size taken from that population).

(Choices A and D) These limits are asymmetric and are therefore inconsistent with a normal distribution curve around the mean.

(Choice B) Approximately 99.7% of all observations lie within 3 SDs of the mean (3.5-6.5 ng/mL).

(Choice E) Approximately 68% of all observations lie within 1 SD of the mean (4.5-5.5 ng/mL).

Educational objective:
In a normal (bell-shaped) distribution curve, 68% of observations lie within 1 standard deviation (SD) of the mean, 95% of observations lie within 2 SDs of the mean, and 99.7% of observations lie within 3 SDs of the mean.

Biostatistics	Biostatistics & Epidemiology	Normal distribution
Subject	System	Topic

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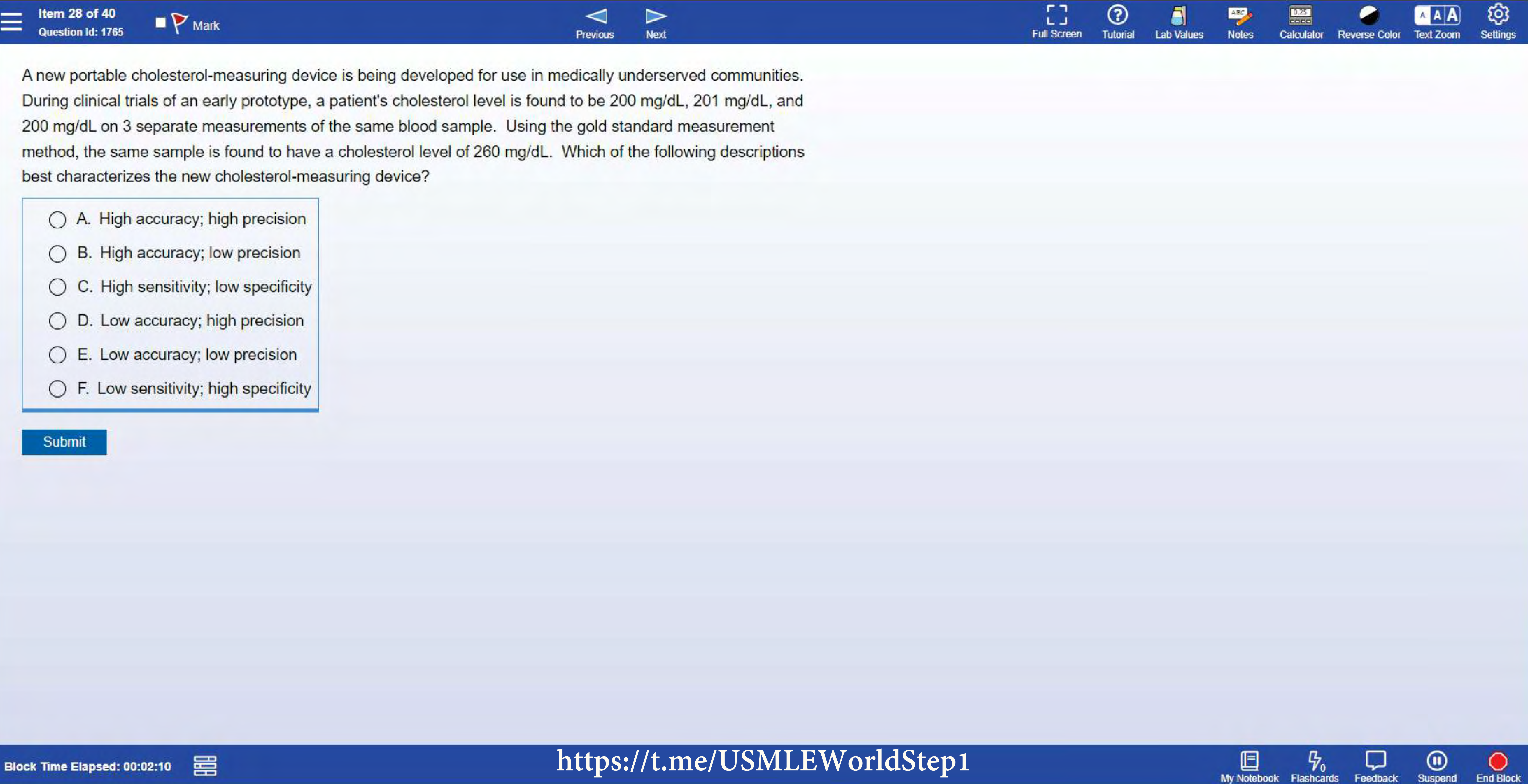
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A new portable cholesterol-measuring device is being developed for use in medically underserved communities. During clinical trials of an early prototype, a patient's cholesterol level is found to be 200 mg/dL, 201 mg/dL, and 200 mg/dL on 3 separate measurements of the same blood sample. Using the gold standard measurement method, the same sample is found to have a cholesterol level of 260 mg/dL. Which of the following descriptions best characterizes the new cholesterol-measuring device?

○ A. High accuracy; high precision
○ B. High accuracy; low precision
○ C. High sensitivity; low specificity
○ D. Low accuracy; high precision
○ E. Low accuracy; low precision
○ F. Low sensitivity; high specificity

Submit

A new portable cholesterol-measuring device is being developed for use in medically underserved communities. During clinical trials of an early prototype, a patient's cholesterol level is found to be 200 mg/dL, 201 mg/dL, and 200 mg/dL on 3 separate measurements of the same blood sample. Using the gold standard measurement method, the same sample is found to have a cholesterol level of 260 mg/dL. Which of the following descriptions best characterizes the new cholesterol-measuring device?

○ A. High accuracy; high precision (0%)
✗ ● B. High accuracy; low precision (7%)
○ C. High sensitivity; low specificity (0%)
✓ ○ D. Low accuracy; high precision (89%)
○ E. Low accuracy; low precision (1%)
○ F. Low sensitivity; high specificity (0%)

Incorrect
Correct answer
D

89%
Answered correctly

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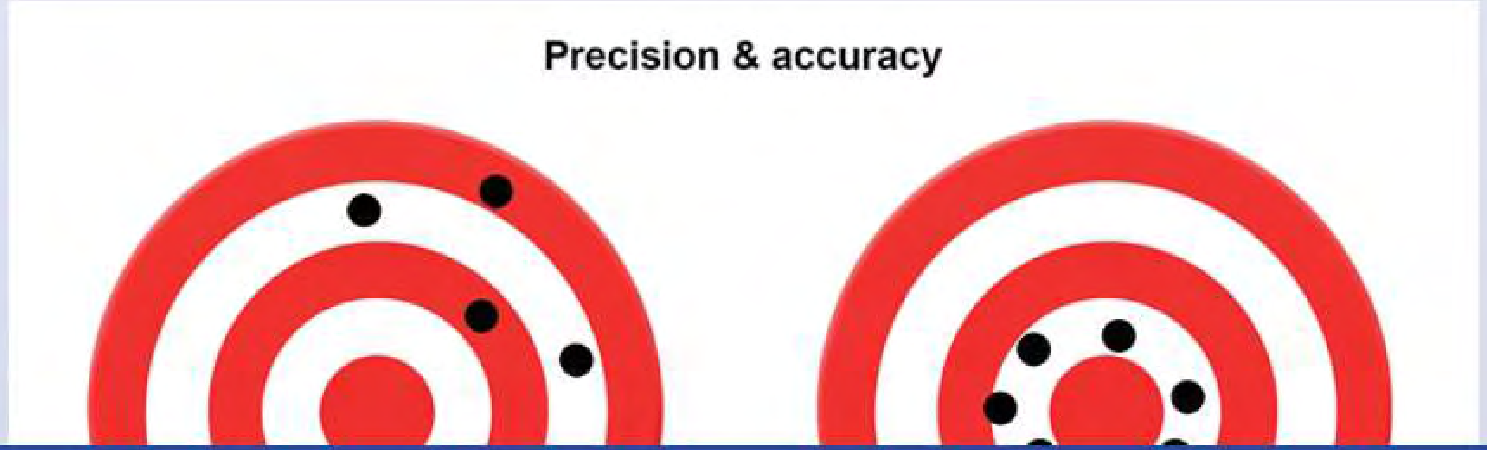
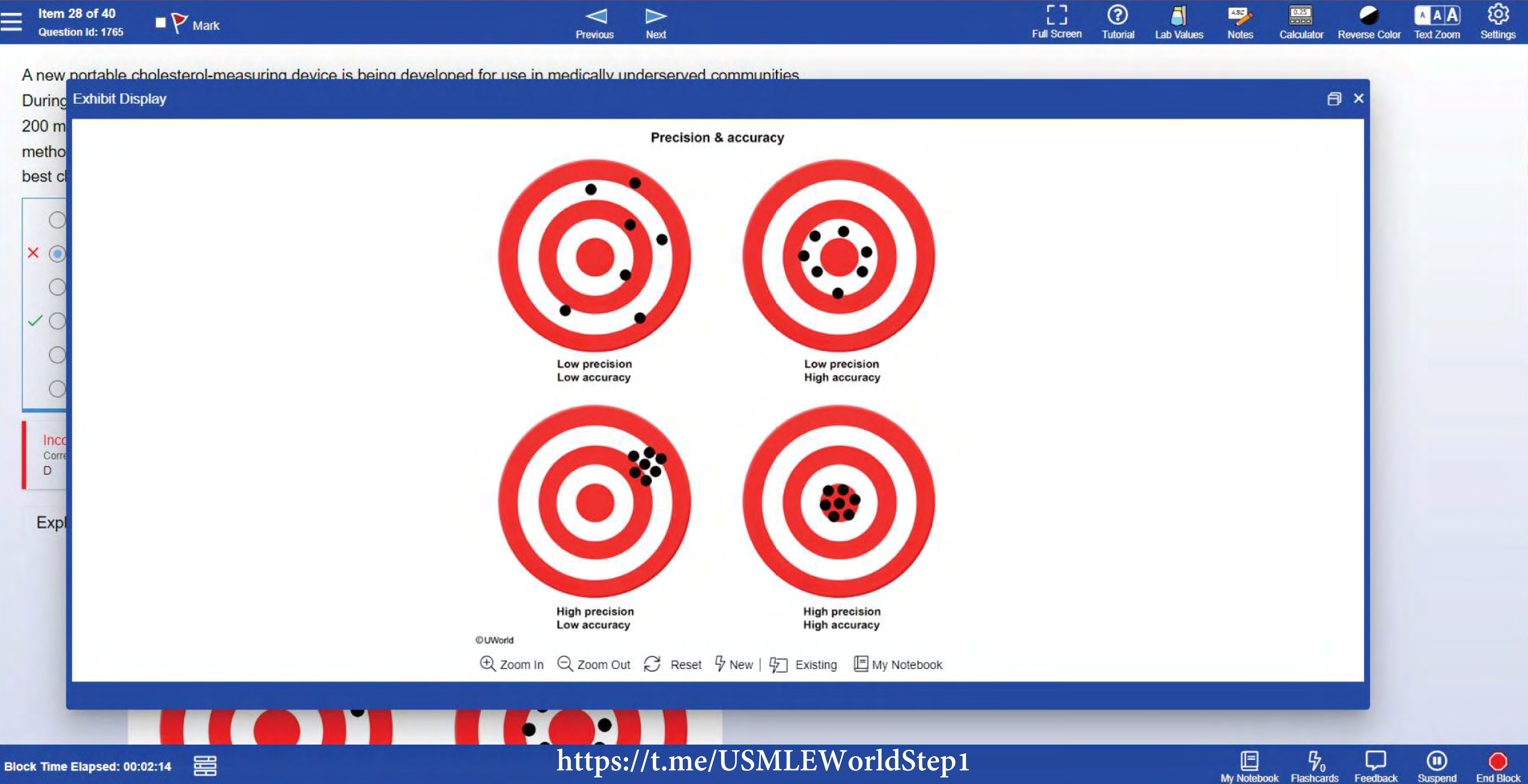
Explanation



Precision & accuracy



A new portable cholesterol-measuring device is being developed for use in medically underserved communities.

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Precision & accuracy

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High precision
Low accuracy
High precision
High accuracy

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- **Precision** (reliability) is the ability of a test to reproduce identical or similar results with repeated measurements (bottom half of figure).
- **Accuracy** (validity) is the ability of a test to measure what it is supposed to measure. For a new test to be accurate, its results should be equivalent to the results obtained with a gold standard (eg, best conventional test available) on the same individual (right half of figure).

In this case, repeated measurements of the same blood sample yielded **nearly identical values**; therefore, the new device has **high precision**. However, none of the measurements with the new device were equivalent to the results obtained with the gold standard (ie, the measurements are **incorrect**), meaning the new device has **low accuracy**.

(Choices C and F) Sensitivity is defined as the percentage of diseased individuals who are correctly identified (ie, proportion of subjects who have a positive test among all those with disease), whereas specificity is defined as the percentage of healthy individuals who are correctly identified (ie, proportion of subjects who have a negative test among all those without disease). Poor accuracy or precision can lead to low test sensitivity and specificity. However, no information is provided to determine the sensitivity or specificity of the new device compared to the gold standard test.

Educational objective:

A precise tool is one that consistently provides very similar or the same value when measuring a fixed quantity. An accurate tool is one that provides a measurement identical or similar to the actual value (as reflected in a gold standard measurement).

Biostatistics	Biostatistics & Epidemiology	Accuracy and precision
Subject	System	Topic

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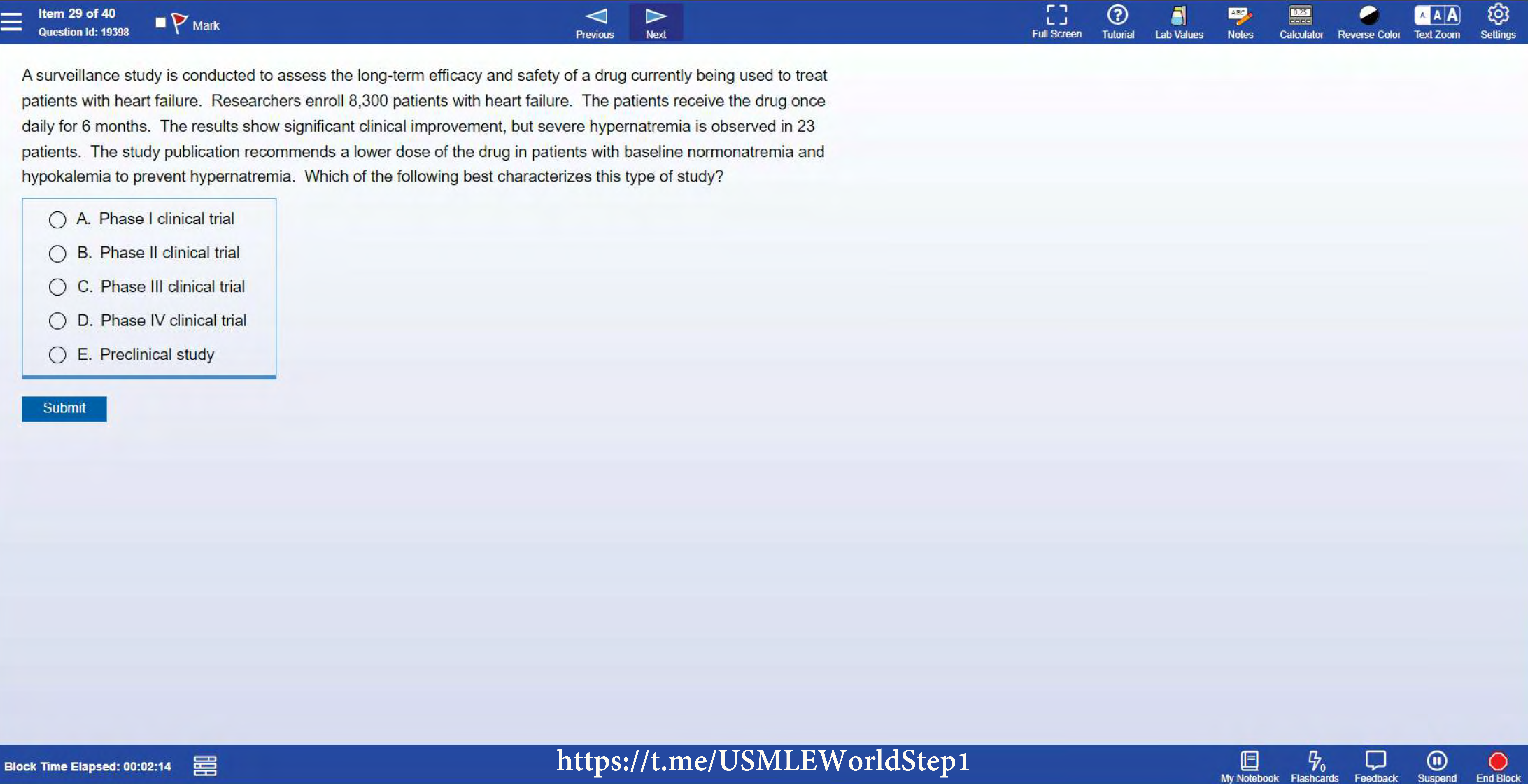
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A surveillance study is conducted to assess the long-term efficacy and safety of a drug currently being used to treat patients with heart failure. Researchers enroll 8,300 patients with heart failure. The patients receive the drug once daily for 6 months. The results show significant clinical improvement, but severe hypernatremia is observed in 23 patients. The study publication recommends a lower dose of the drug in patients with baseline normonatremia and hypokalemia to prevent hypernatremia. Which of the following best characterizes this type of study?

○ A. Phase I clinical trial
○ B. Phase II clinical trial
○ C. Phase III clinical trial
○ D. Phase IV clinical trial
○ E. Preclinical study

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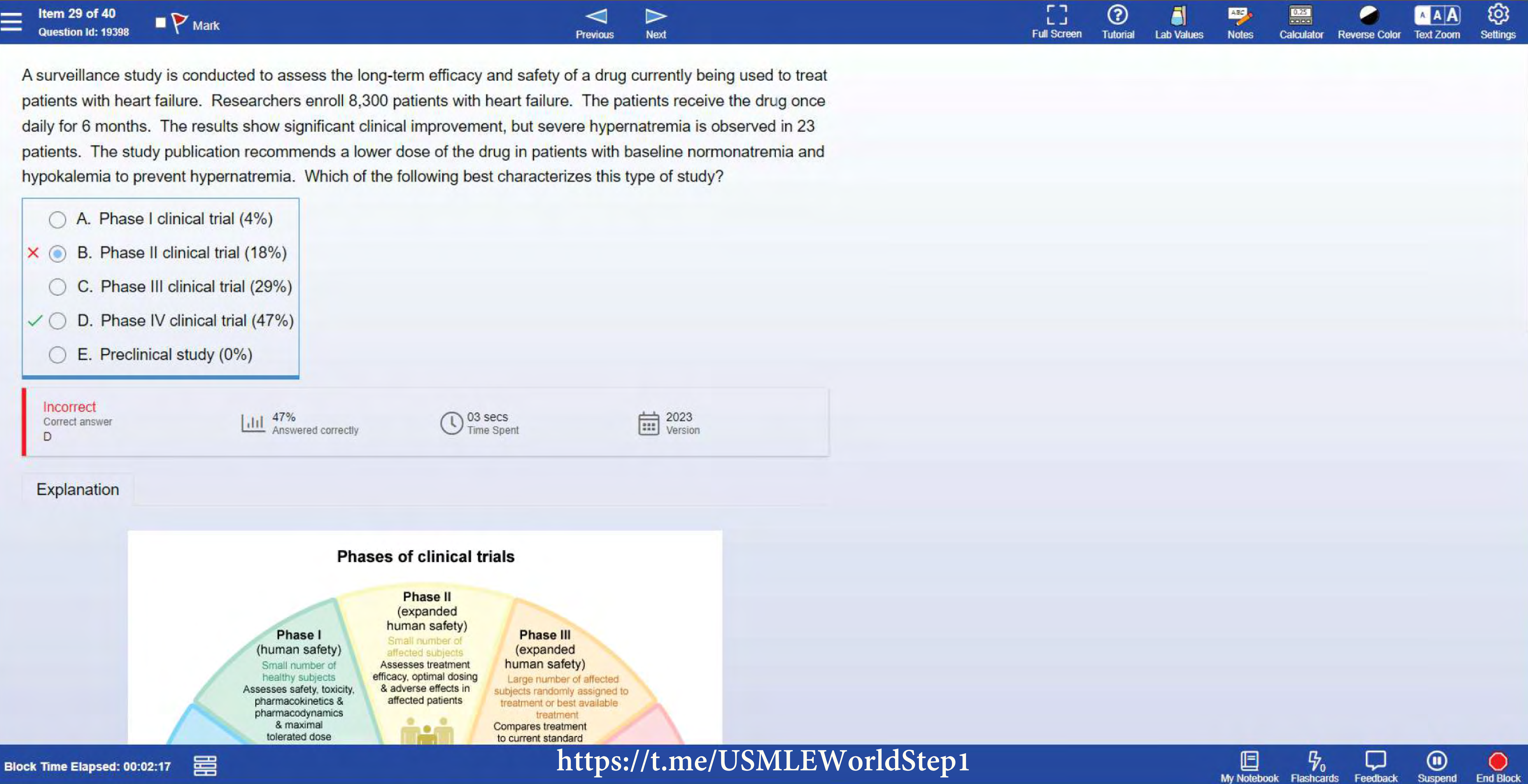
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Question Id: 19398

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○ A. Phase I clinical trial (4%)
✗ ● B. Phase II clinical trial (18%)
○ C. Phase III clinical trial (29%)
✓ ○ D. Phase IV clinical trial (47%)
○ E. Preclinical study (0%)

Incorrect
Correct answer
D

47%
Answered correctly

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Explanation

Phases of clinical trials

Phase I
(human safety)
Small number of healthy subjects
Assesses safety, toxicity, pharmacokinetics & pharmacodynamics & maximal tolerated dose
Phase II
(expanded human safety)
Small number of affected subjects
Assesses treatment efficacy, optimal dosing & adverse effects in affected patients
Phase III
(expanded human safety)
Large number of affected subjects randomly assigned to treatment or best available treatment
Compares treatment to current standard

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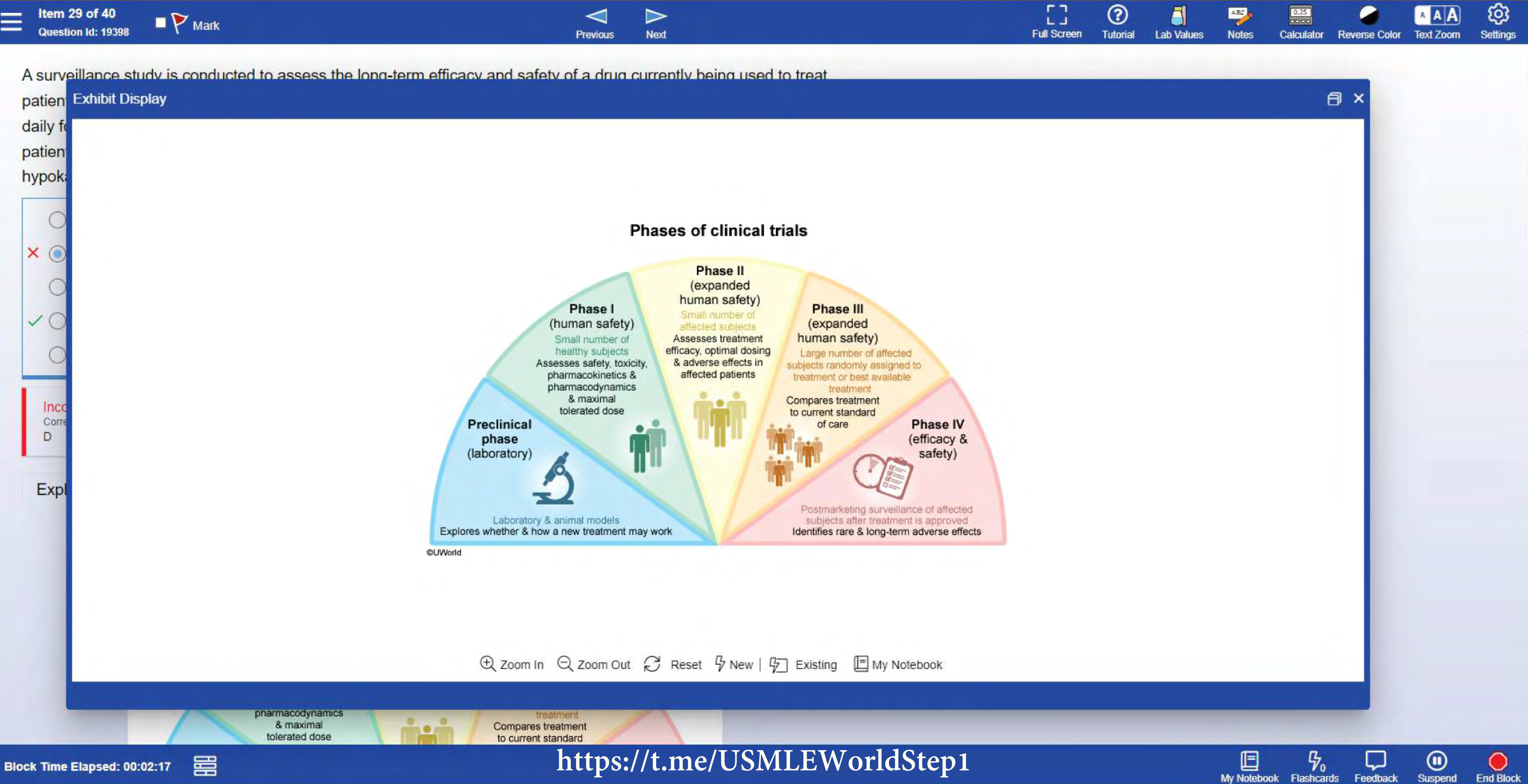
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A surveillance study is conducted to assess the long-term efficacy and safety of a drug currently being used to treat

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Phases of clinical trials

Preclinical phase (laboratory)
Laboratory & animal models
Explores whether & how a new treatment may work

Phase I (human safety)
Small number of healthy subjects
Assesses safety, toxicity, pharmacokinetics & pharmacodynamics & maximal tolerated dose

Phase II (expanded human safety)
Small number of affected subjects
Assesses treatment efficacy, optimal dosing & adverse effects in affected patients

Phase III (expanded human safety)
Large number of affected subjects randomly assigned to treatment or best available treatment
Compares treatment to current standard of care

Phase IV (efficacy & safety)
Postmarketing surveillance of affected subjects after treatment is approved
Identifies rare & long-term adverse effects

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pharmacodynamics & maximal tolerated dose
treatment
Compares treatment to current standard

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Efficacy and safety of new drugs are established during the **clinical trials process**. New drugs are approved by a regulatory body (ie, Food and Drug Administration) following review of **phase I-III** trials. Phases differ in size, objective, and participant selection.

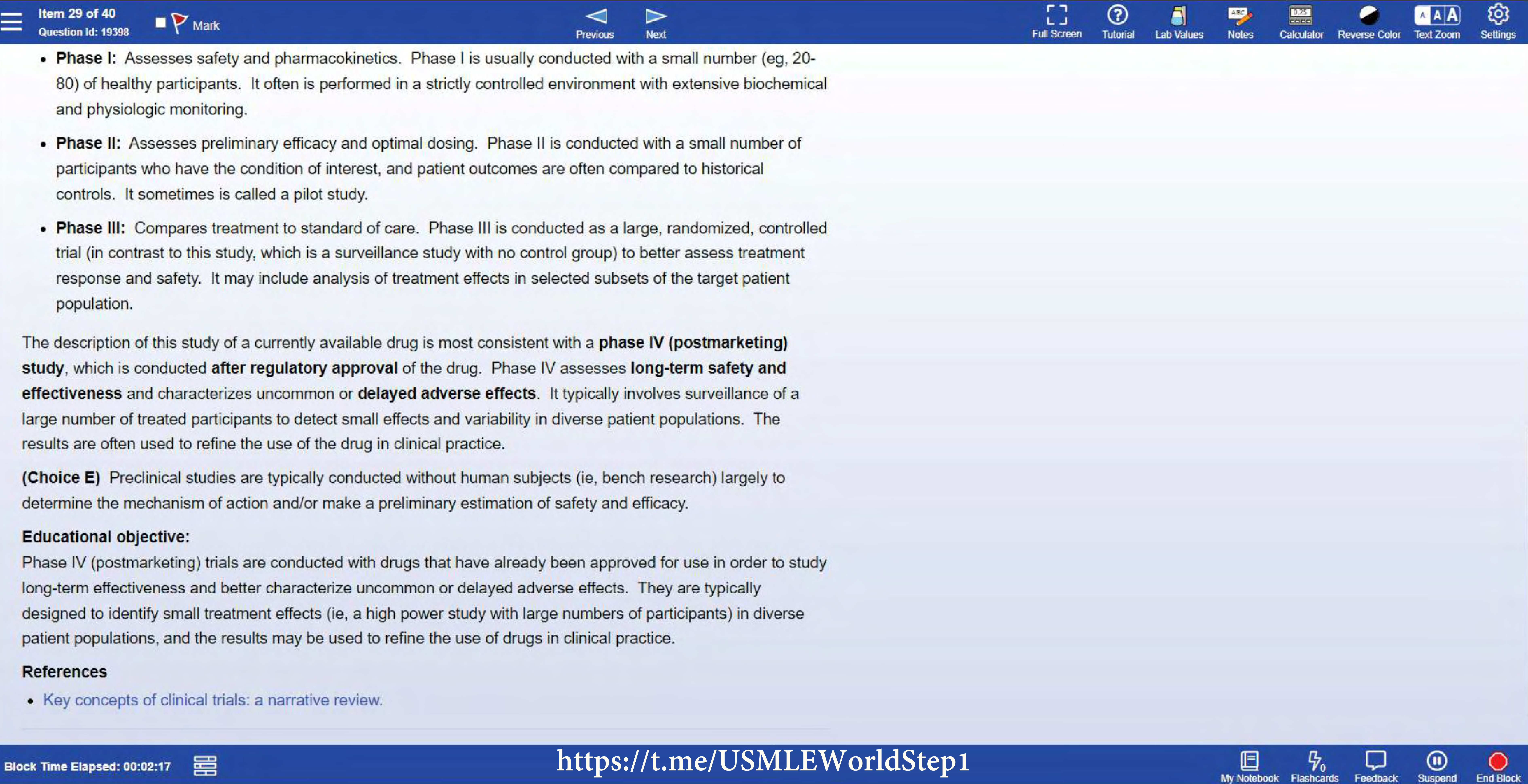
- **Phase I:** Assesses safety and pharmacokinetics. Phase I is usually conducted with a small number (eg, 20-80) of healthy participants. It often is performed in a strictly controlled environment with extensive biochemical and physiologic monitoring.
- **Phase II:** Assesses preliminary efficacy and optimal dosing. Phase II is conducted with a small number of participants who have the condition of interest, and patient outcomes are often compared to historical controls. It sometimes is called a pilot study.
- **Phase III:** Compares treatment to standard of care. Phase III is conducted as a large, randomized, controlled trial (in contrast to this study, which is a surveillance study with no control group) to better assess treatment response and safety. It may include analysis of treatment effects in selected subsets of the target patient population.

The description of this study of a currently available drug is most consistent with a **phase IV (postmarketing) study**, which is conducted **after regulatory approval** of the drug. Phase IV assesses **long-term safety and effectiveness** and characterizes uncommon or **delayed adverse effects**. It typically involves surveillance of a large number of treated participants to detect small effects and variability in diverse patient populations. The results are often used to refine the use of the drug in clinical practice.

(Choice E) Preclinical studies are typically conducted without human subjects (ie, bench research) largely to determine the mechanism of action and/or make a preliminary estimation of safety and efficacy.

Educational objective:

Phase IV (postmarketing) trials are conducted with drugs that have already been approved for use in order to study long-term effectiveness and better characterize uncommon or delayed adverse effects. They are typically designed to identify small treatment effects (ie, a high power study with large numbers of participants) in diverse patient populations, and the results may be used to refine the use of drugs in clinical practice.



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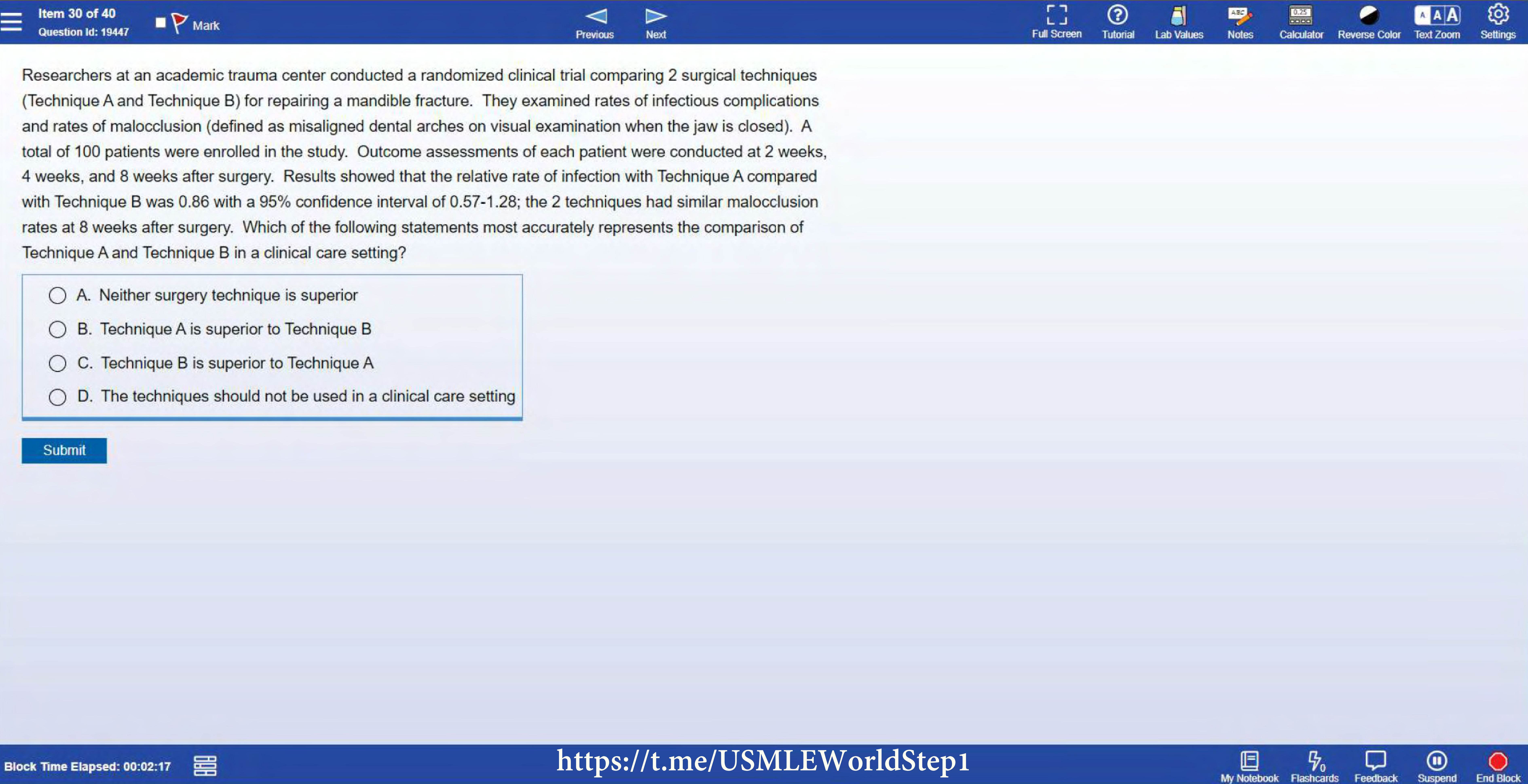
References

- Key concepts of clinical trials: a narrative review.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Researchers at an academic trauma center conducted a randomized clinical trial comparing 2 surgical techniques (Technique A and Technique B) for repairing a mandible fracture. They examined rates of infectious complications and rates of malocclusion (defined as misaligned dental arches on visual examination when the jaw is closed). A total of 100 patients were enrolled in the study. Outcome assessments of each patient were conducted at 2 weeks, 4 weeks, and 8 weeks after surgery. Results showed that the relative rate of infection with Technique A compared with Technique B was 0.86 with a 95% confidence interval of 0.57-1.28; the 2 techniques had similar malocclusion rates at 8 weeks after surgery. Which of the following statements most accurately represents the comparison of Technique A and Technique B in a clinical care setting?

○ A. Neither surgery technique is superior

○ B. Technique A is superior to Technique B

○ C. Technique B is superior to Technique A

○ D. The techniques should not be used in a clinical care setting

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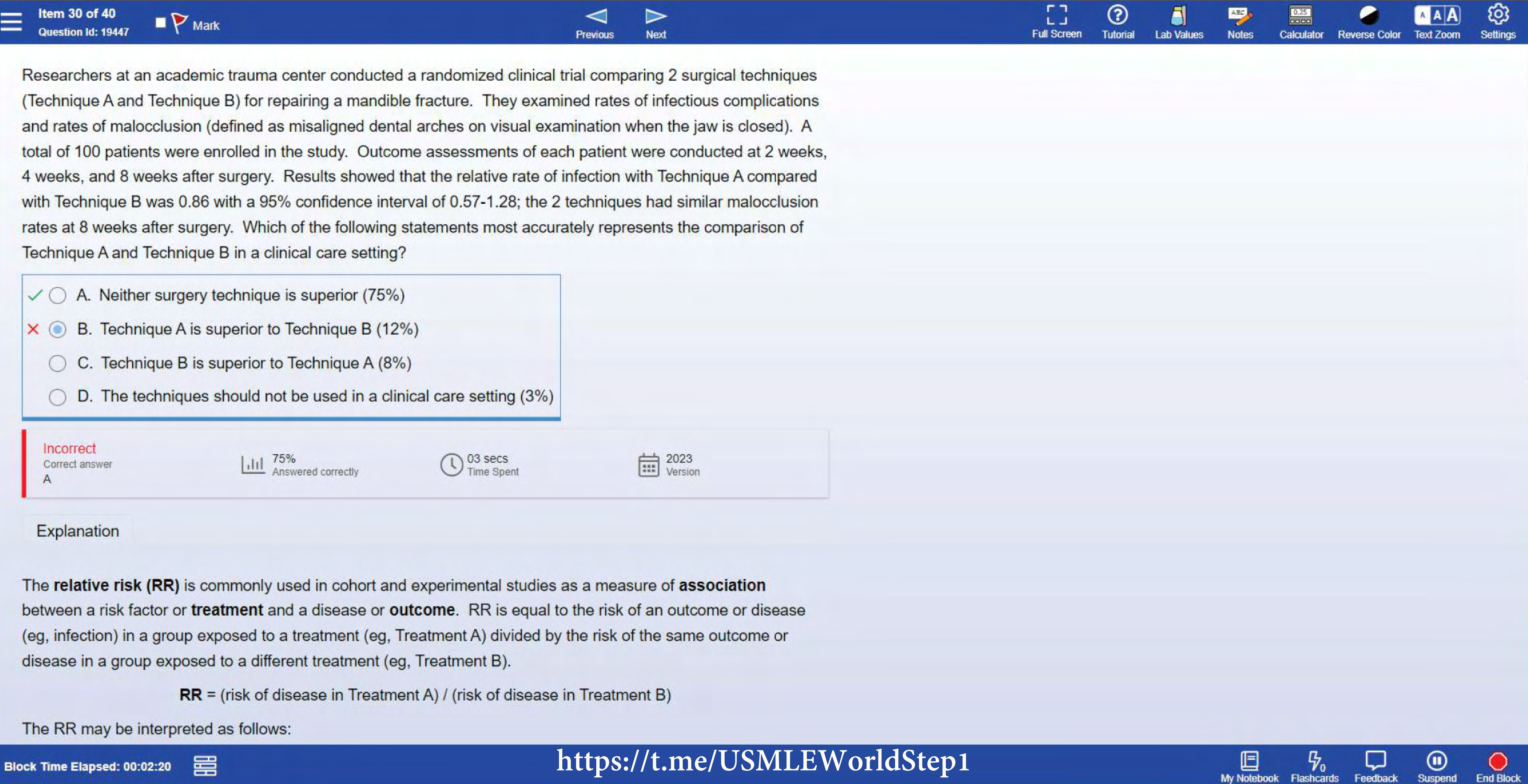
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✓ ○ A. Neither surgery technique is superior (75%)
✗ ● B. Technique A is superior to Technique B (12%)
○ C. Technique B is superior to Technique A (8%)
○ D. The techniques should not be used in a clinical care setting (3%)

Incorrect
Correct answer
A

75%
Answered correctly

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Explanation

The **relative risk (RR)** is commonly used in cohort and experimental studies as a measure of **association** between a risk factor or **treatment** and a disease or **outcome**. RR is equal to the risk of an outcome or disease (eg, infection) in a group exposed to a treatment (eg, Treatment A) divided by the risk of the same outcome or disease in a group exposed to a different treatment (eg, Treatment B).

RR = (risk of disease in Treatment A) / (risk of disease in Treatment B)

The RR may be interpreted as follows:

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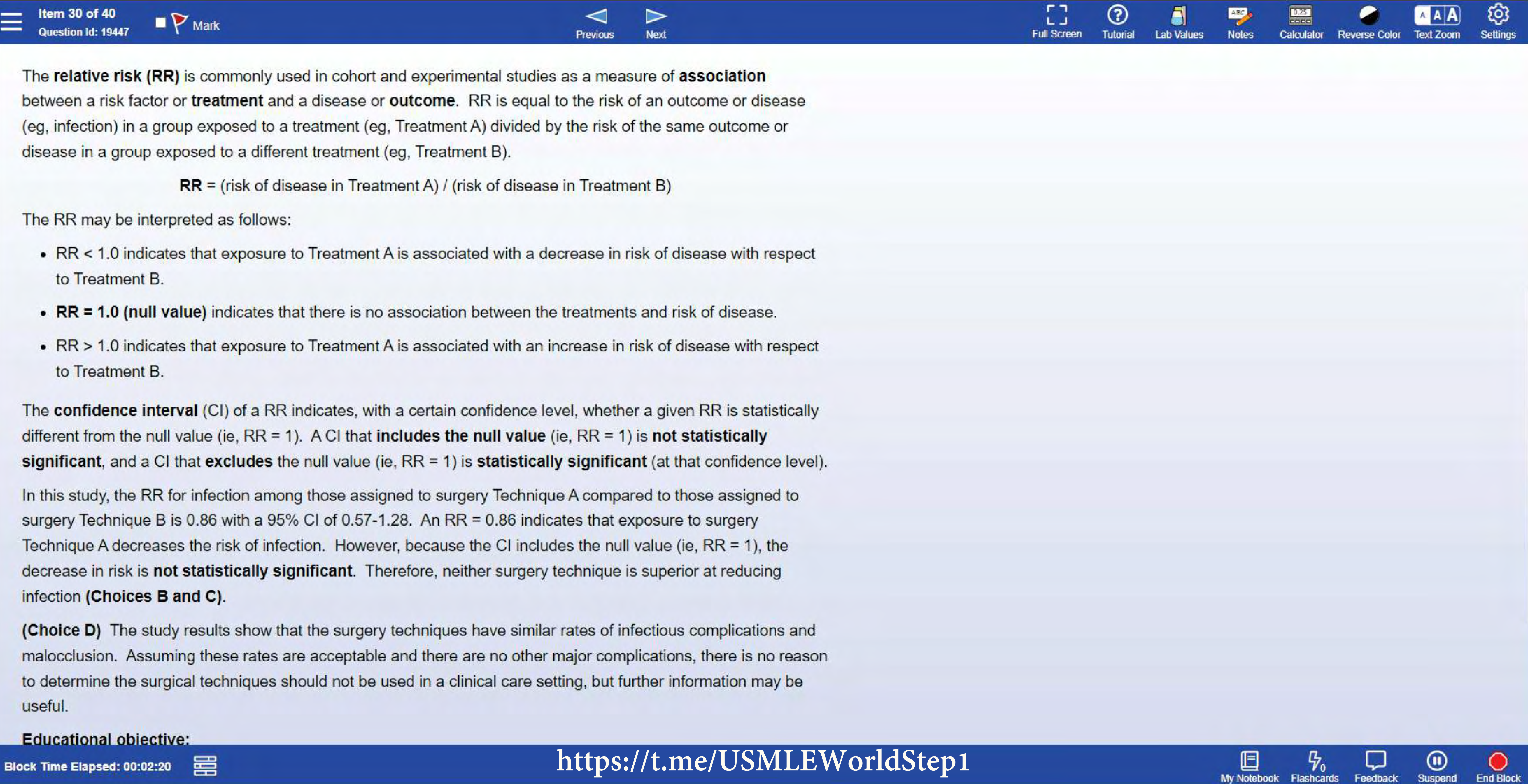


The **relative risk (RR)** is commonly used in cohort and experimental studies as a measure of **association** between a risk factor or **treatment** and a disease or **outcome**. RR is equal to the risk of an outcome or disease (eg, infection) in a group exposed to a treatment (eg, Treatment A) divided by the risk of the same outcome or disease in a group exposed to a different treatment (eg, Treatment B).

RR = (risk of disease in Treatment A) / (risk of disease in Treatment B)

The RR may be interpreted as follows:

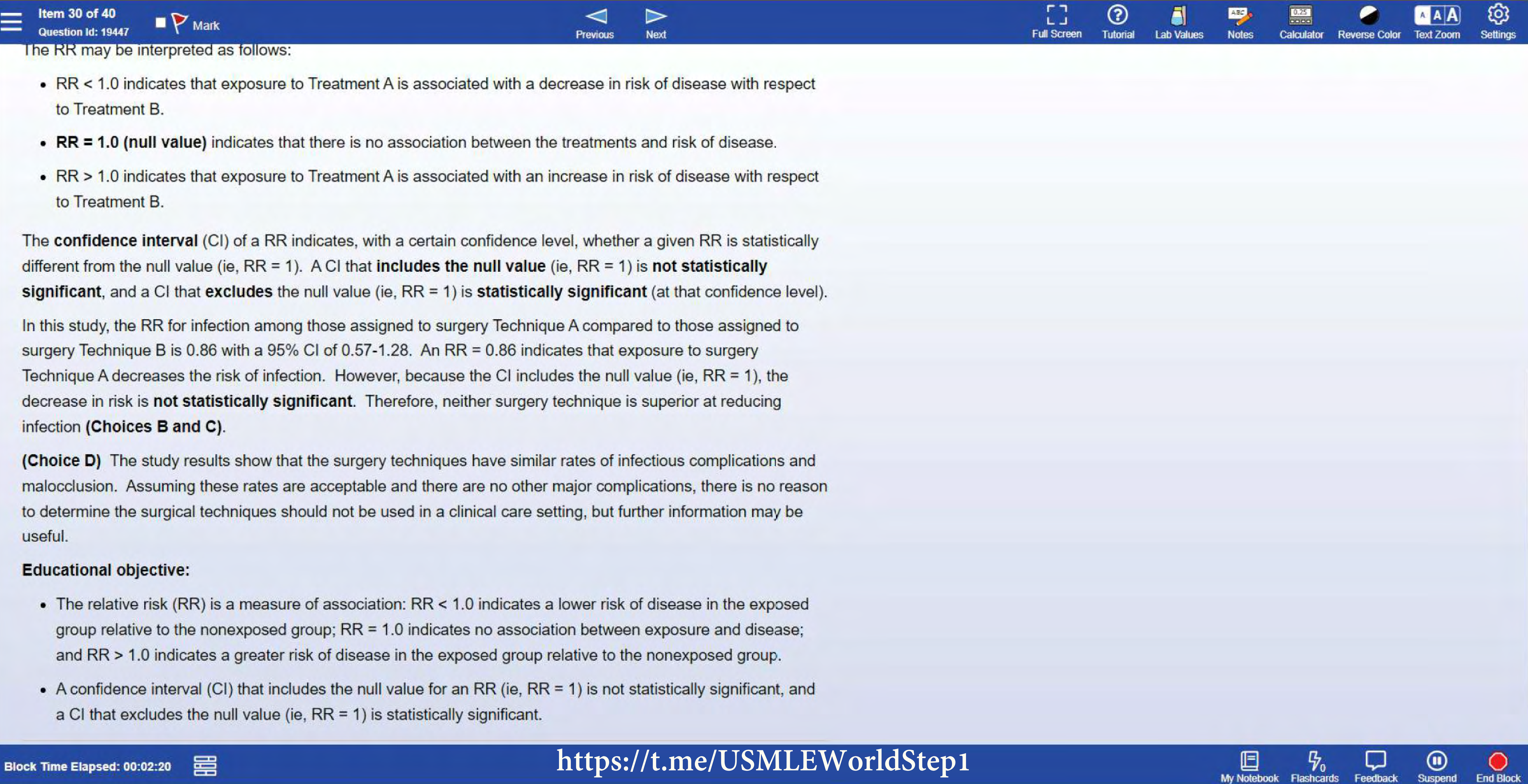
- RR < 1.0 indicates that exposure to Treatment A is associated with a decrease in risk of disease with respect to Treatment B.
- **RR = 1.0 (null value)** indicates that there is no association between the treatments and risk of disease.
- RR > 1.0 indicates that exposure to Treatment A is associated with an increase in risk of disease with respect to Treatment B.

The **confidence interval** (CI) of a RR indicates, with a certain confidence level, whether a given RR is statistically different from the null value (ie, RR = 1). A CI that **includes the null value** (ie, RR = 1) is **not statistically significant**, and a CI that **excludes** the null value (ie, RR = 1) is **statistically significant** (at that confidence level).

In this study, the RR for infection among those assigned to surgery Technique A compared to those assigned to surgery Technique B is 0.86 with a 95% CI of 0.57-1.28. An RR = 0.86 indicates that exposure to surgery Technique A decreases the risk of infection. However, because the CI includes the null value (ie, RR = 1), the decrease in risk is **not statistically significant**. Therefore, neither surgery technique is superior at reducing infection **(Choices B and C)**.

(Choice D) The study results show that the surgery techniques have similar rates of infectious complications and malocclusion. Assuming these rates are acceptable and there are no other major complications, there is no reason to determine the surgical techniques should not be used in a clinical care setting, but further information may be useful.

Educational objective:



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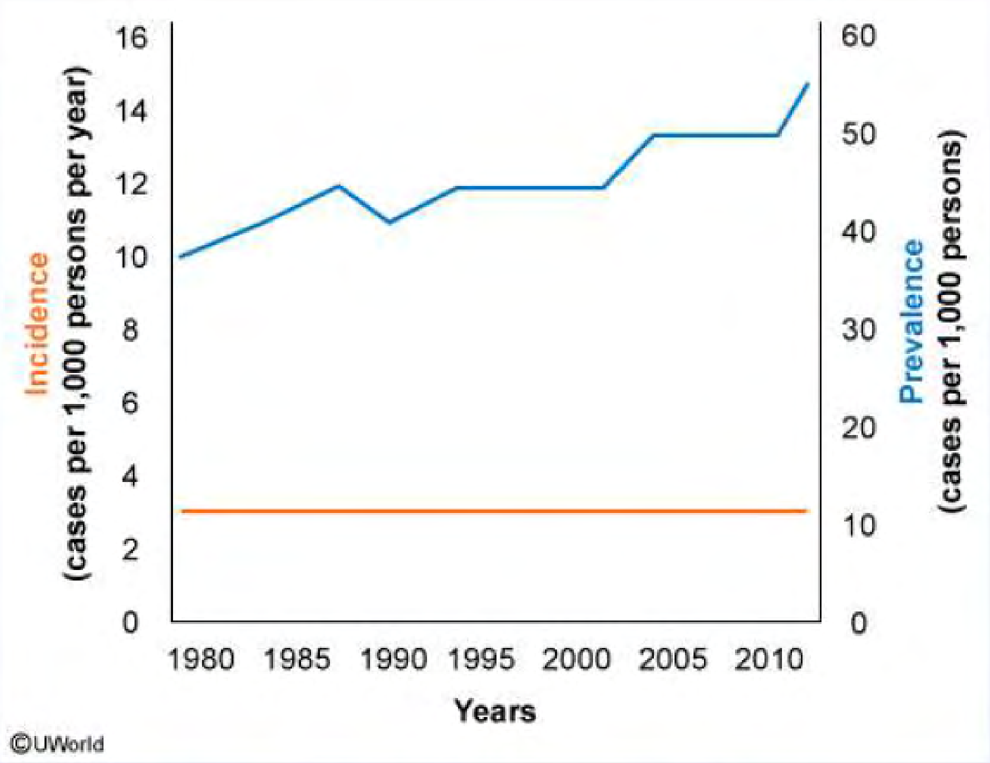
(Choice D) The study results show that the surgery techniques have similar rates of infectious complications and malocclusion. Assuming these rates are acceptable and there are no other major complications, there is no reason to determine the surgical techniques should not be used in a clinical care setting, but further information may be useful.

Educational objective:

- The relative risk (RR) is a measure of association: RR < 1.0 indicates a lower risk of disease in the exposed group relative to the nonexposed group; RR = 1.0 indicates no association between exposure and disease; and RR > 1.0 indicates a greater risk of disease in the exposed group relative to the nonexposed group.
- A confidence interval (CI) that includes the null value for an RR (ie, RR = 1) is not statistically significant, and a CI that excludes the null value (ie, RR = 1) is statistically significant.

An epidemiological study is initiated to assess the impact of type II diabetes mellitus in a large population with little migration. Disease incidence and prevalence are monitored and recorded as the number of cases per 1,000 individuals over a 30-year period.



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Which of the following is the most likely explanation for the change in disease prevalence seen in the graph?

○ A. Decreased hospitalization rate

○ B. High mortality in diabetics

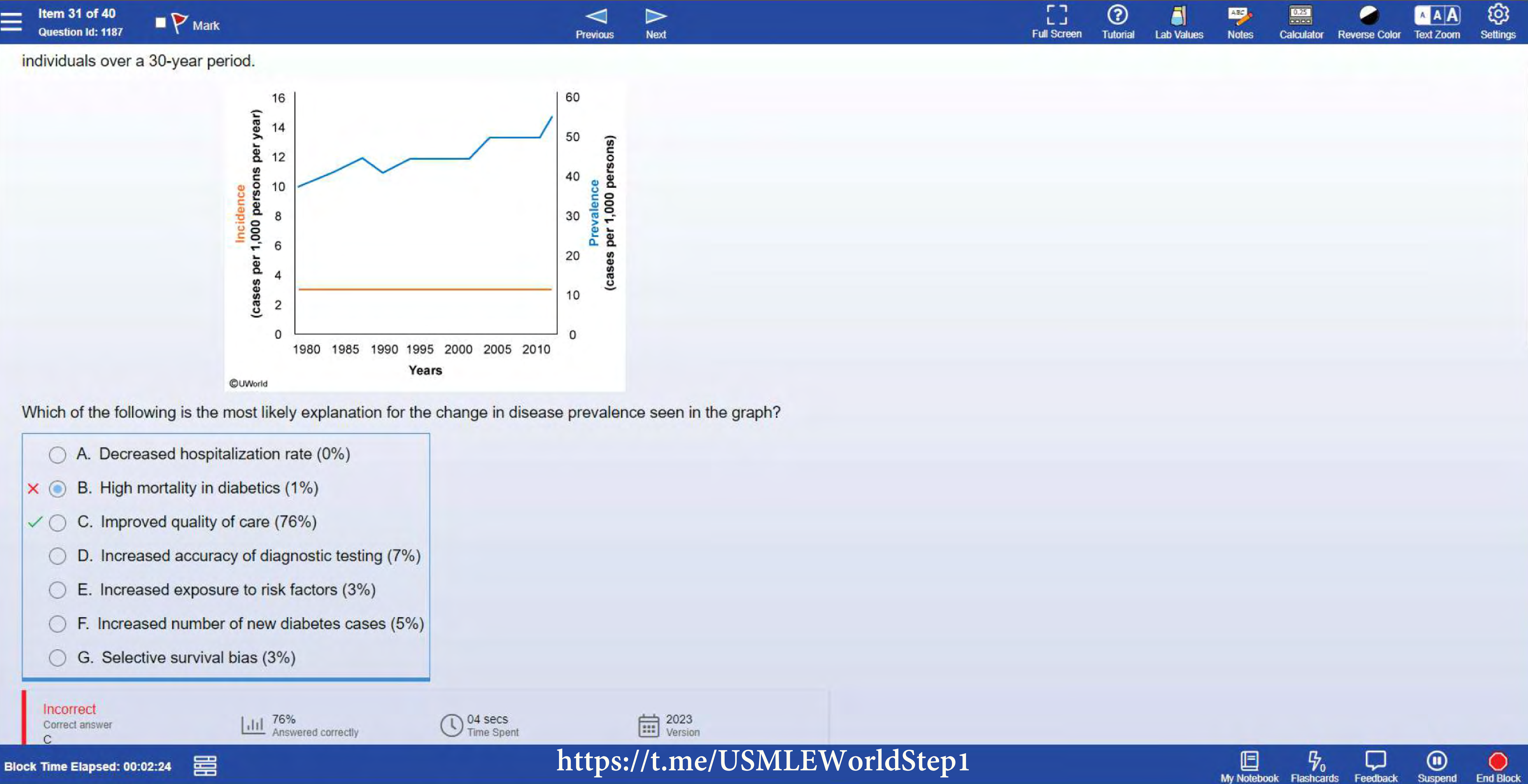
○ C. Improved quality of care

○ D. Increased accuracy of diagnostic testing

○ E. Increased exposure to risk factors

○ F. Increased number of new diabetes cases

○ G. Selective survival bias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individuals over a 30-year period.

16
14
12
10
8
6
4
2
0
Incidence
(cases per 1,000 persons per year)
60
50
40
30
20
10
0
Prevalence
(cases per 1,000 persons)
1980
1985
1990
1995
2000
2005
2010
Years
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Which of the following is the most likely explanation for the change in disease prevalence seen in the graph?

- ○ A. Decreased hospitalization rate (0%)
- ✗ ● B. High mortality in diabetics (1%)
- ✓ ○ C. Improved quality of care (76%)
- ○ D. Increased accuracy of diagnostic testing (7%)
- ○ E. Increased exposure to risk factors (3%)
- ○ F. Increased number of new diabetes cases (5%)
- ○ G. Selective survival bias (3%)

Incorrect
Correct answer
C

76%
Answered correctly

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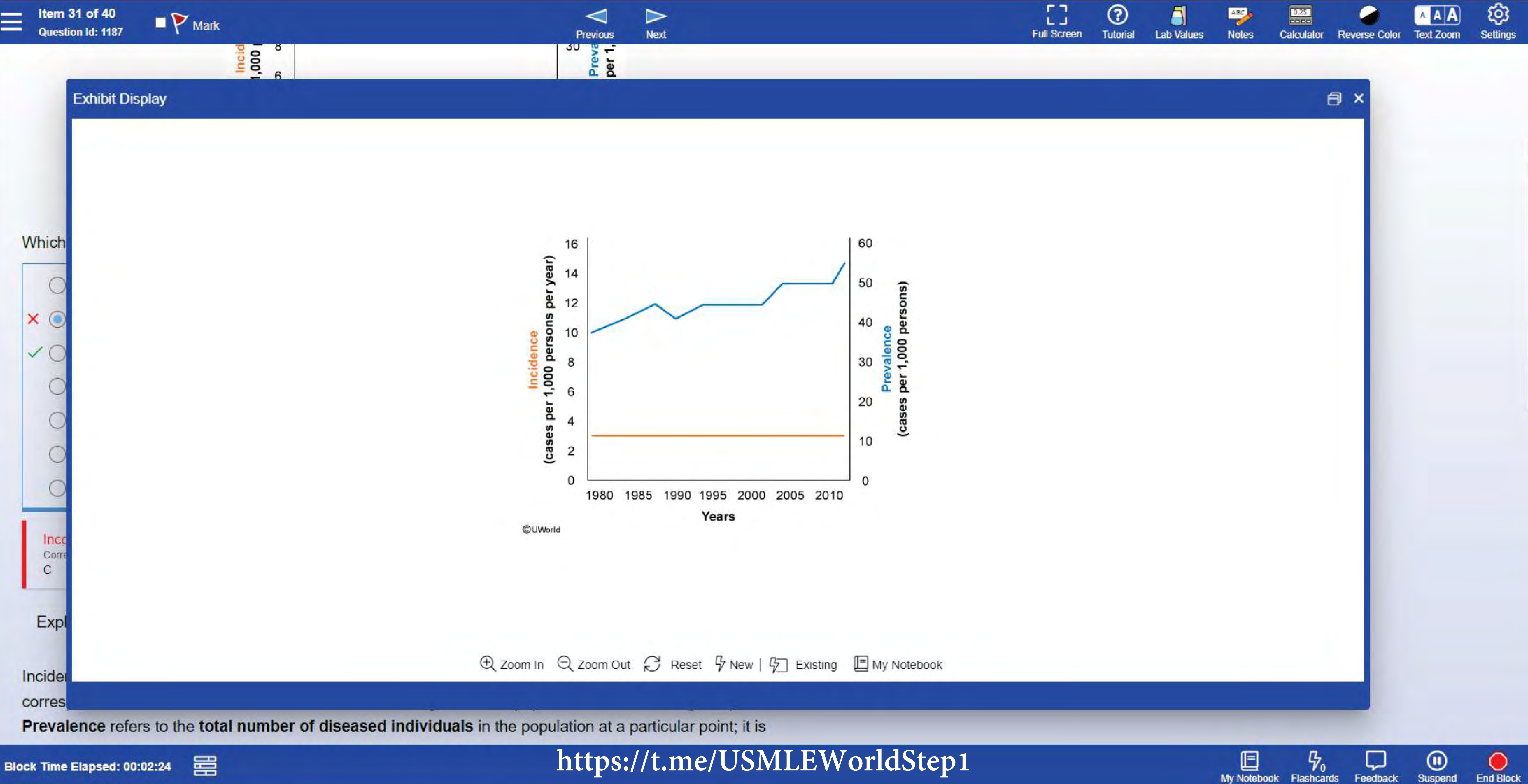
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16
14
12
10
8
6
4
2
0
Incidence
(cases per 1,000 persons per year)
60
50
40
30
20
10
0
Prevalence
(cases per 1,000 persons)
1980
1985
1990
1995
2000
2005
2010
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Zoom In
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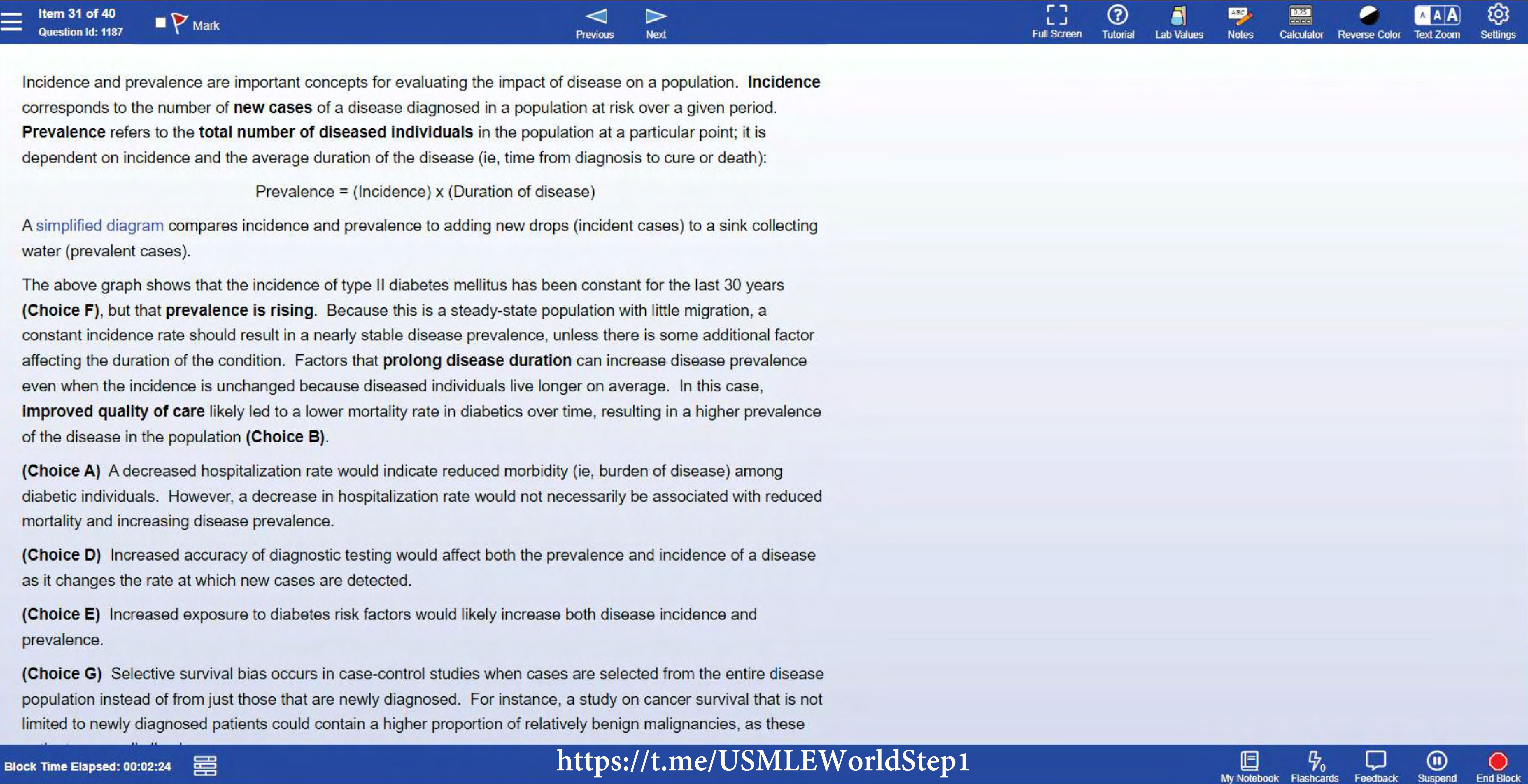
Prevalence refers to the **total number of diseased individuals** in the population at a particular point; it is



Incidence and prevalence are important concepts for evaluating the impact of disease on a population. **Incidence** corresponds to the number of **new cases** of a disease diagnosed in a population at risk over a given period. **Prevalence** refers to the **total number of diseased individuals** in the population at a particular point; it is dependent on incidence and the average duration of the disease (ie, time from diagnosis to cure or death):

Prevalence = (Incidence) x (Duration of disease)

A simplified diagram compares incidence and prevalence to adding new drops (incident cases) to a sink collecting water (prevalent cases).

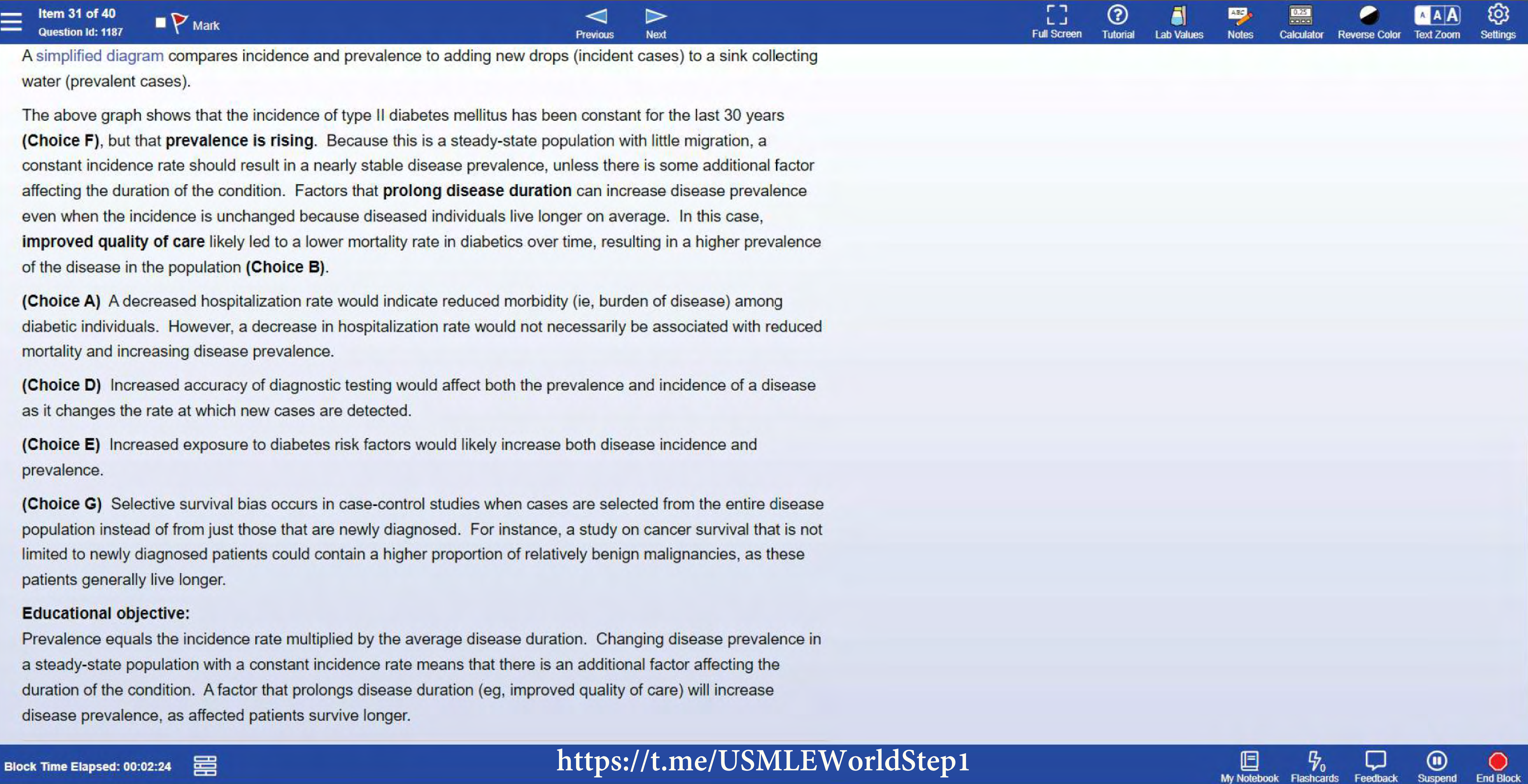
The above graph shows that the incidence of type II diabetes mellitus has been constant for the last 30 years **(Choice F)**, but that **prevalence is rising**. Because this is a steady-state population with little migration, a constant incidence rate should result in a nearly stable disease prevalence, unless there is some additional factor affecting the duration of the condition. Factors that **prolong disease duration** can increase disease prevalence even when the incidence is unchanged because diseased individuals live longer on average. In this case, **improved quality of care** likely led to a lower mortality rate in diabetics over time, resulting in a higher prevalence of the disease in the population **(Choice B)**.

(Choice A) A decreased hospitalization rate would indicate reduced morbidity (ie, burden of disease) among diabetic individuals. However, a decrease in hospitalization rate would not necessarily be associated with reduced mortality and increasing disease prevalence.

(Choice D) Increased accuracy of diagnostic testing would affect both the prevalence and incidence of a disease as it changes the rate at which new cases are detected.

(Choice E) Increased exposure to diabetes risk factors would likely increase both disease incidence and prevalence.

(Choice G) Selective survival bias occurs in case-control studies when cases are selected from the entire disease population instead of from just those that are newly diagnosed. For instance, a study on cancer survival that is not limited to newly diagnosed patients could contain a higher proportion of relatively benign malignancies, as these



A simplified diagram compares incidence and prevalence to adding new drops (incident cases) to a sink collecting water (prevalent cases).

The above graph shows that the incidence of type II diabetes mellitus has been constant for the last 30 years **(Choice F)**, but that **prevalence is rising**. Because this is a steady-state population with little migration, a constant incidence rate should result in a nearly stable disease prevalence, unless there is some additional factor affecting the duration of the condition. Factors that **prolong disease duration** can increase disease prevalence even when the incidence is unchanged because diseased individuals live longer on average. In this case, **improved quality of care** likely led to a lower mortality rate in diabetics over time, resulting in a higher prevalence of the disease in the population **(Choice B)**.

(Choice A) A decreased hospitalization rate would indicate reduced morbidity (ie, burden of disease) among diabetic individuals. However, a decrease in hospitalization rate would not necessarily be associated with reduced mortality and increasing disease prevalence.

(Choice D) Increased accuracy of diagnostic testing would affect both the prevalence and incidence of a disease as it changes the rate at which new cases are detected.

(Choice E) Increased exposure to diabetes risk factors would likely increase both disease incidence and prevalence.

(Choice G) Selective survival bias occurs in case-control studies when cases are selected from the entire disease population instead of from just those that are newly diagnosed. For instance, a study on cancer survival that is not limited to newly diagnosed patients could contain a higher proportion of relatively benign malignancies, as these patients generally live longer.

Educational objective:

Prevalence equals the incidence rate multiplied by the average disease duration. Changing disease prevalence in a steady-state population with a constant incidence rate means that there is an additional factor affecting the duration of the condition. A factor that prolongs disease duration (eg, improved quality of care) will increase disease prevalence, as affected patients survive longer.

Prevalence refers to the **total number of diseased individuals** in the population at a particular point; it is dependent on incidence and the average duration of the disease (ie, time from diagnosis to cure or death):

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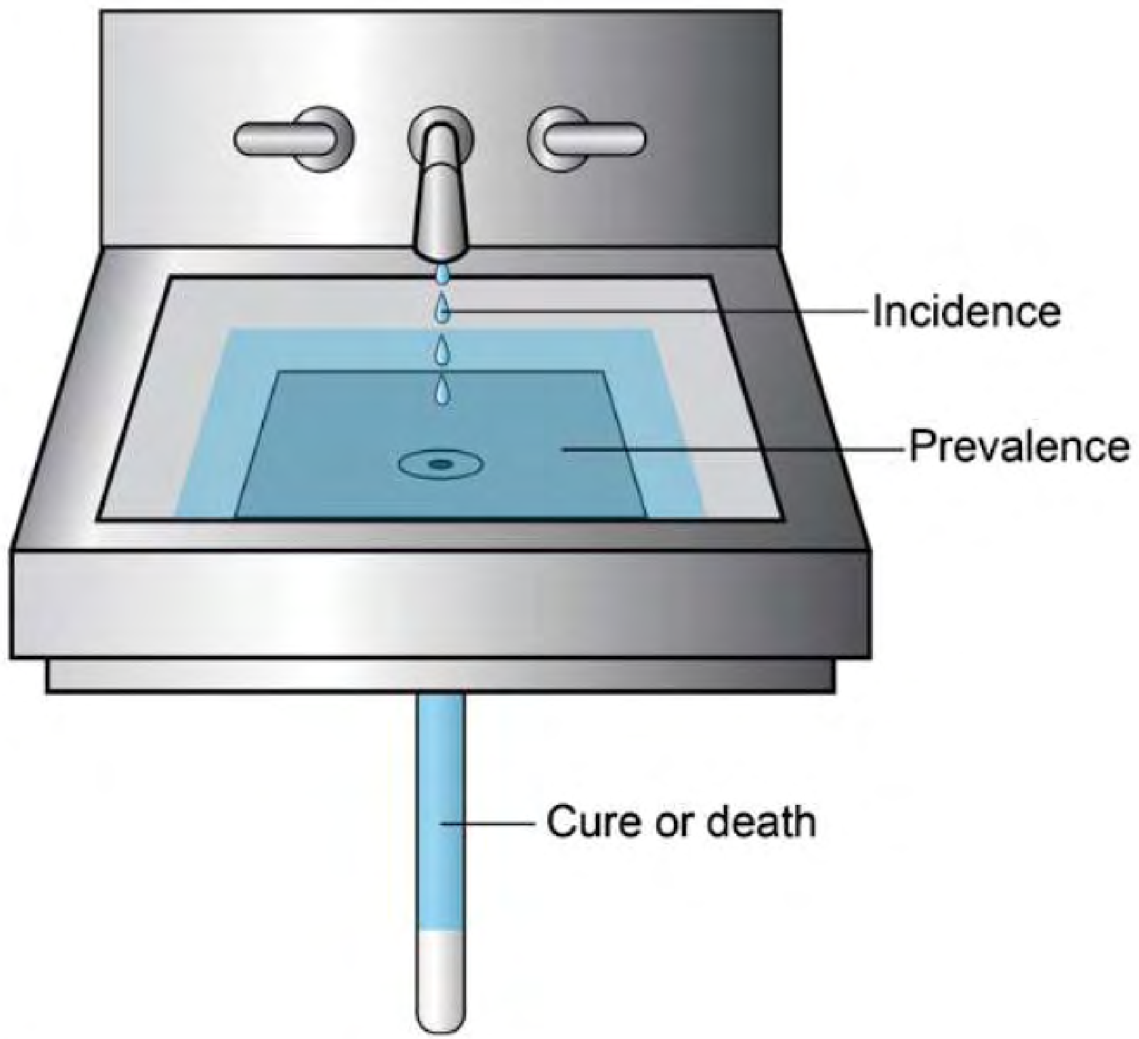
Incidence & prevalence



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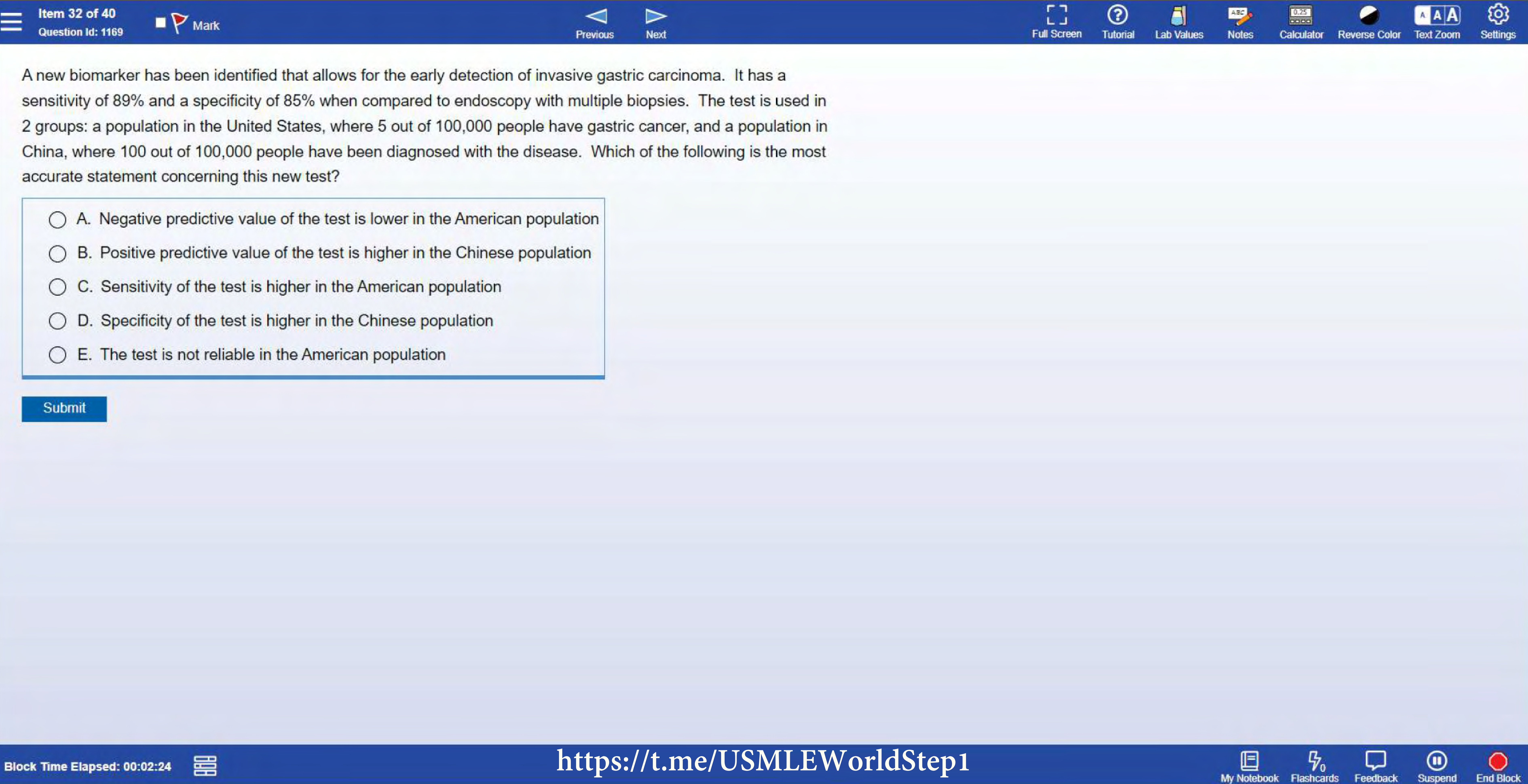
Prevalence equals the incidence rate multiplied by the average disease duration. Changing disease prevalence in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A new biomarker has been identified that allows for the early detection of invasive gastric carcinoma. It has a sensitivity of 89% and a specificity of 85% when compared to endoscopy with multiple biopsies. The test is used in 2 groups: a population in the United States, where 5 out of 100,000 people have gastric cancer, and a population in China, where 100 out of 100,000 people have been diagnosed with the disease. Which of the following is the most accurate statement concerning this new test?

- ○ A. Negative predictive value of the test is lower in the American population
- ○ B. Positive predictive value of the test is higher in the Chinese population
- ○ C. Sensitivity of the test is higher in the American population
- ○ D. Specificity of the test is higher in the Chinese population
- ○ E. The test is not reliable in the American population

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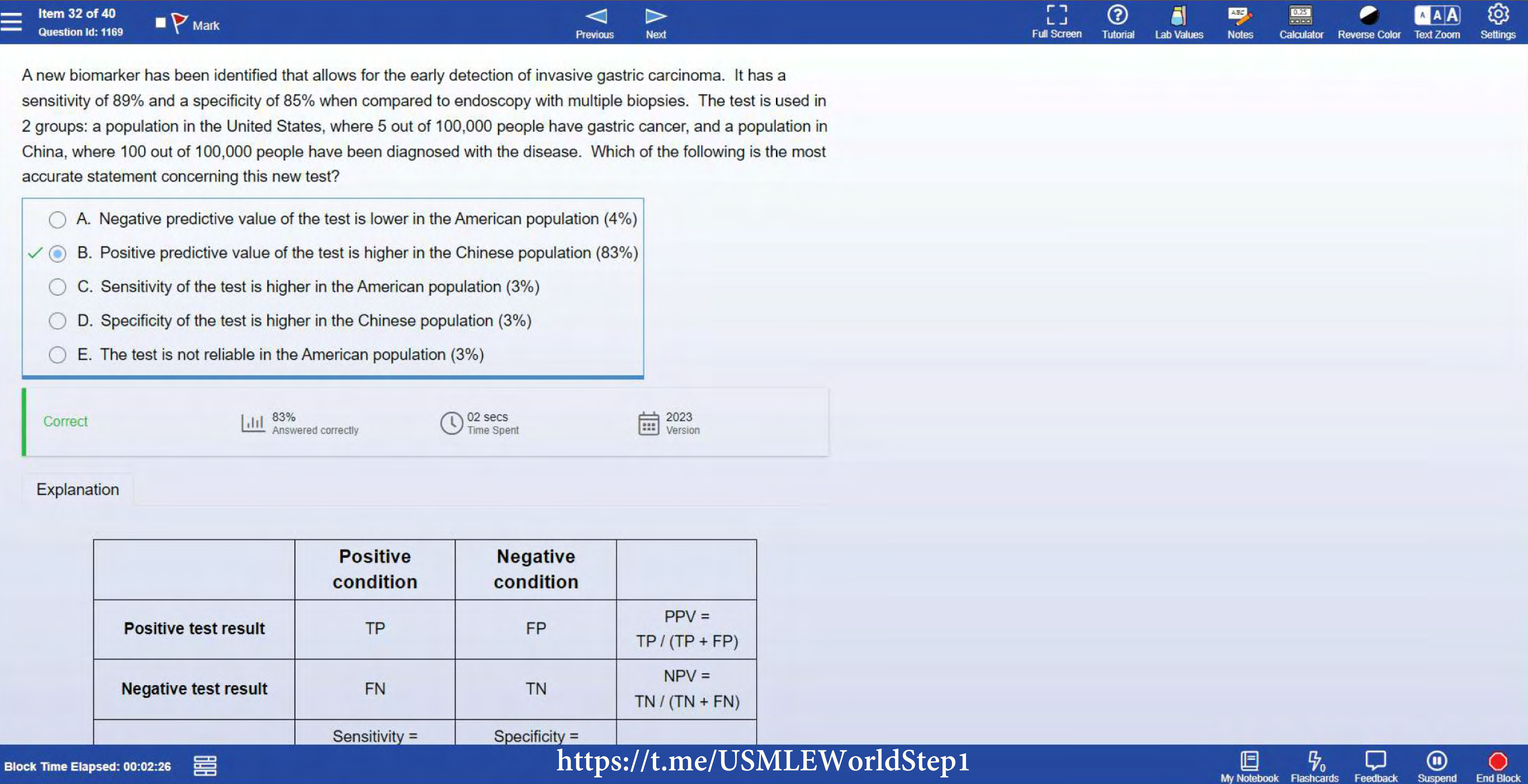
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A new biomarker has been identified that allows for the early detection of invasive gastric carcinoma. It has a sensitivity of 89% and a specificity of 85% when compared to endoscopy with multiple biopsies. The test is used in 2 groups: a population in the United States, where 5 out of 100,000 people have gastric cancer, and a population in China, where 100 out of 100,000 people have been diagnosed with the disease. Which of the following is the most accurate statement concerning this new test?

○ A. Negative predictive value of the test is lower in the American population (4%)

✓ ● B. Positive predictive value of the test is higher in the Chinese population (83%)

○ C. Sensitivity of the test is higher in the American population (3%)

○ D. Specificity of the test is higher in the Chinese population (3%)

○ E. The test is not reliable in the American population (3%)

Correct

83% Answered correctly

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Explanation

	Positive condition	Negative condition	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity =	Specificity =	

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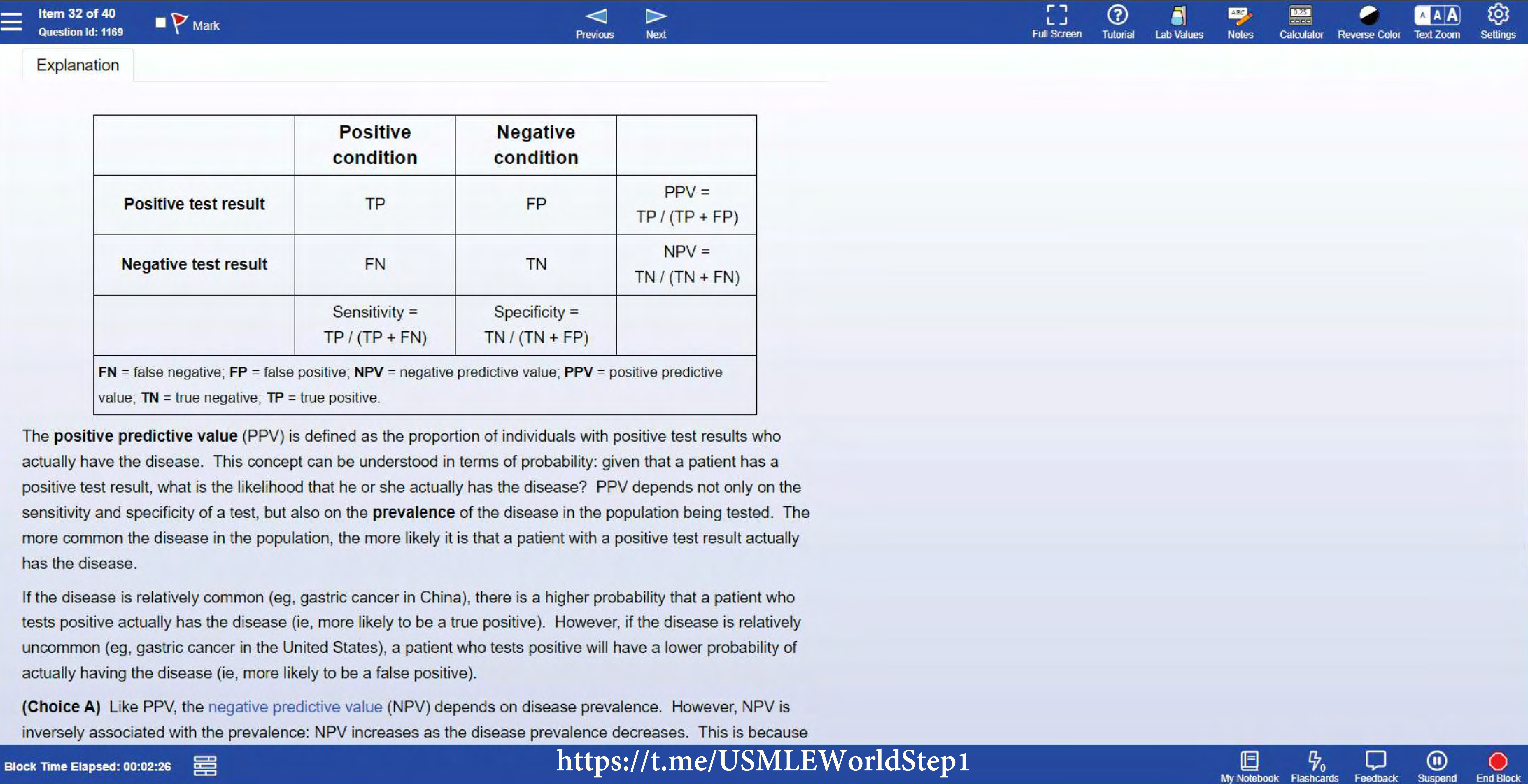
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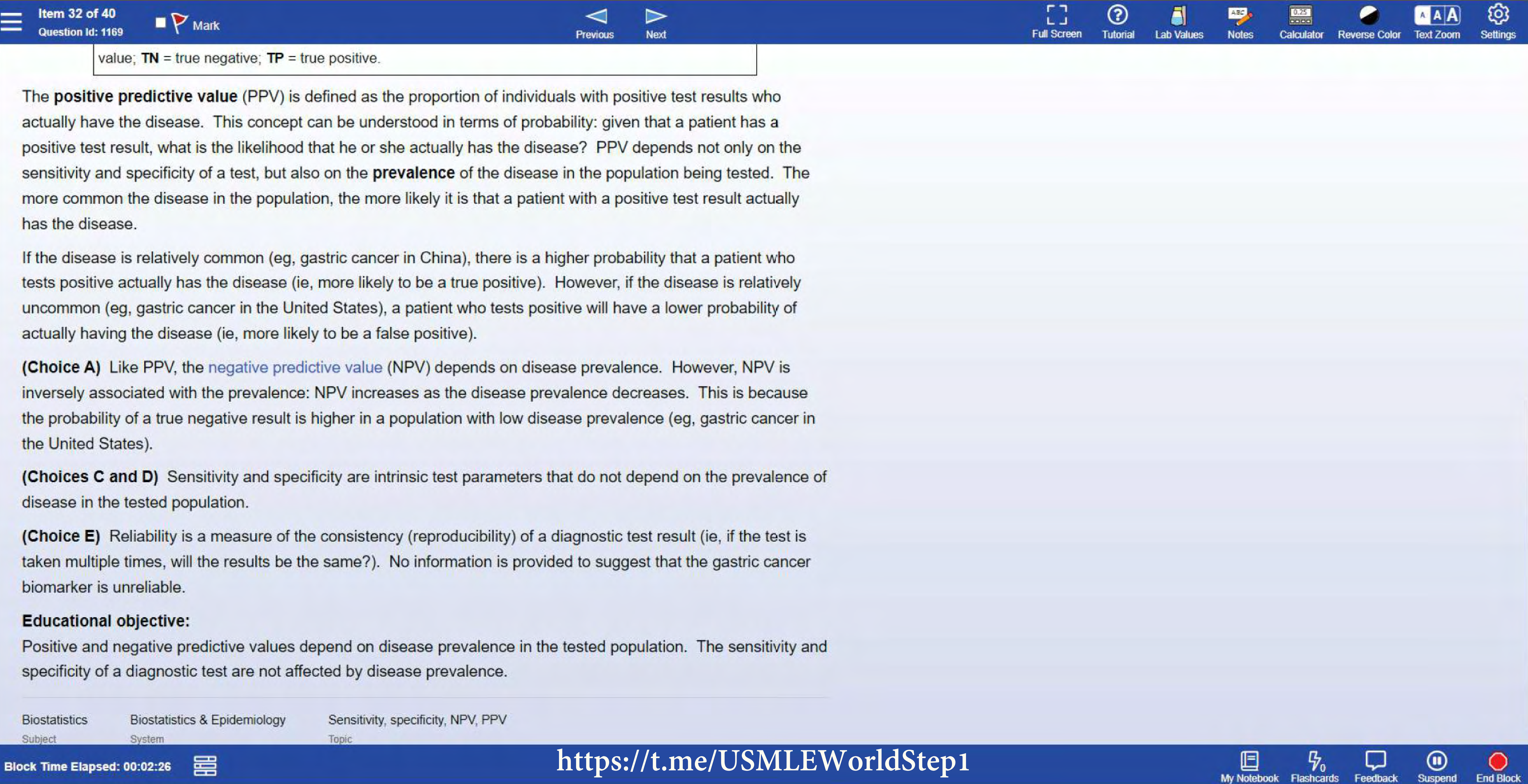
	Positive condition	**Negative condition**	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

The **positive predictive value** (PPV) is defined as the proportion of individuals with positive test results who actually have the disease. This concept can be understood in terms of probability: given that a patient has a positive test result, what is the likelihood that he or she actually has the disease? PPV depends not only on the sensitivity and specificity of a test, but also on the **prevalence** of the disease in the population being tested. The more common the disease in the population, the more likely it is that a patient with a positive test result actually has the disease.

If the disease is relatively common (eg, gastric cancer in China), there is a higher probability that a patient who tests positive actually has the disease (ie, more likely to be a true positive). However, if the disease is relatively uncommon (eg, gastric cancer in the United States), a patient who tests positive will have a lower probability of actually having the disease (ie, more likely to be a false positive).

(Choice A) Like PPV, the negative predictive value (NPV) depends on disease prevalence. However, NPV is inversely associated with the prevalence: NPV increases as the disease prevalence decreases. This is because



value; **TN** = true negative; **TP** = true positive.

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If the disease is relatively common (eg, gastric cancer in China), there is a higher probability that a patient who tests positive actually has the disease (ie, more likely to be a true positive). However, if the disease is relatively uncommon (eg, gastric cancer in the United States), a patient who tests positive will have a lower probability of actually having the disease (ie, more likely to be a false positive).

(Choice A) Like PPV, the negative predictive value (NPV) depends on disease prevalence. However, NPV is inversely associated with the prevalence: NPV increases as the disease prevalence decreases. This is because the probability of a true negative result is higher in a population with low disease prevalence (eg, gastric cancer in the United States).

(Choices C and D) Sensitivity and specificity are intrinsic test parameters that do not depend on the prevalence of disease in the tested population.

(Choice E) Reliability is a measure of the consistency (reproducibility) of a diagnostic test result (ie, if the test is taken multiple times, will the results be the same?). No information is provided to suggest that the gastric cancer biomarker is unreliable.

Educational objective:

Positive and negative predictive values depend on disease prevalence in the tested population. The sensitivity and specificity of a diagnostic test are not affected by disease prevalence.

Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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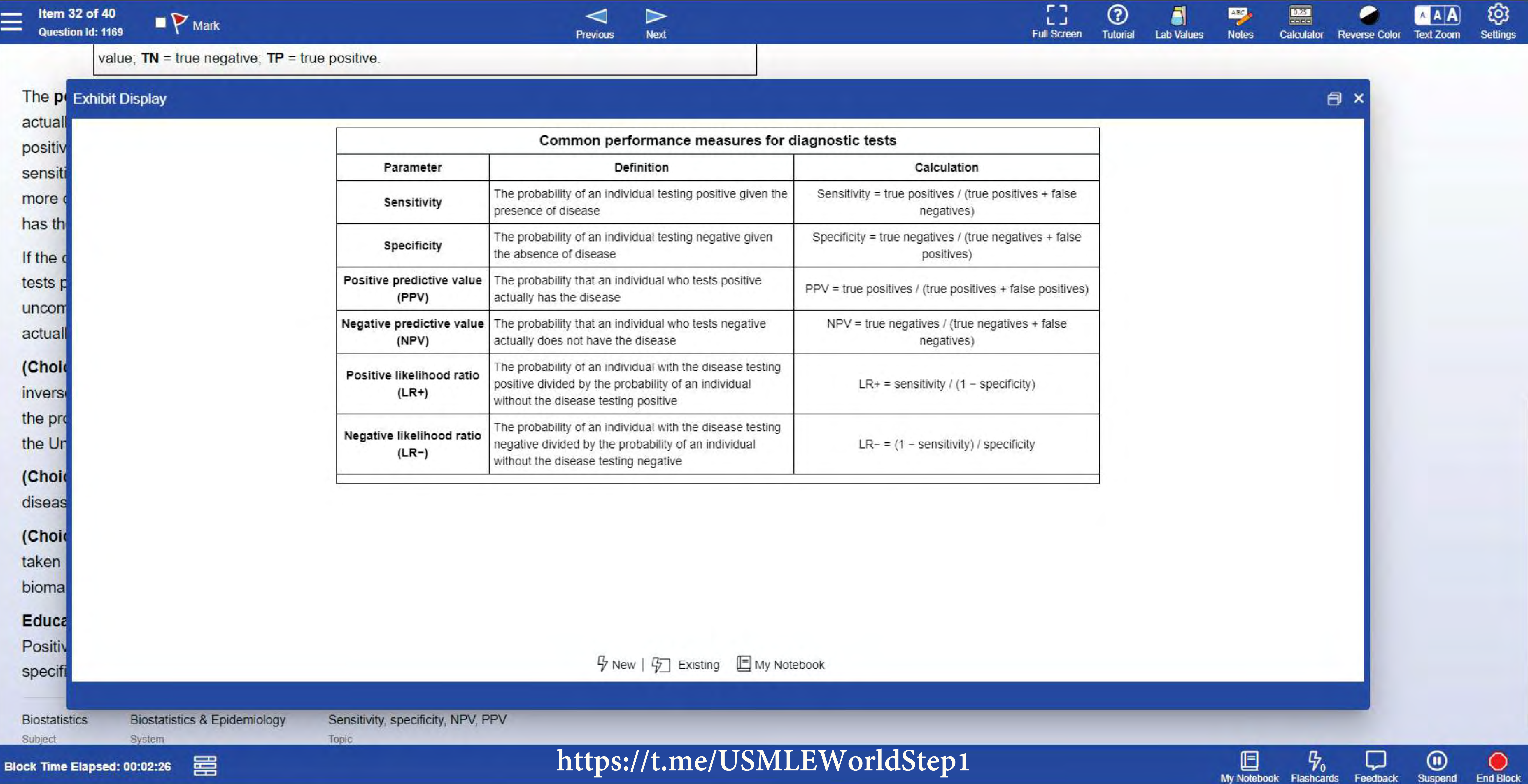
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value; **TN** = true negative; **TP** = true positive.

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Common performance measures for diagnostic tests

Parameter	Definition	Calculation
Sensitivity	The probability of an individual testing positive given the presence of disease	Sensitivity = true positives / (true positives + false negatives)
Specificity	The probability of an individual testing negative given the absence of disease	Specificity = true negatives / (true negatives + false positives)
Positive predictive value (PPV)	The probability that an individual who tests positive actually has the disease	PPV = true positives / (true positives + false positives)
Negative predictive value (NPV)	The probability that an individual who tests negative actually does not have the disease	NPV = true negatives / (true negatives + false negatives)
Positive likelihood ratio (LR+)	The probability of an individual with the disease testing positive divided by the probability of an individual without the disease testing positive	LR+ = sensitivity / (1 − specificity)
Negative likelihood ratio (LR−)	The probability of an individual with the disease testing negative divided by the probability of an individual without the disease testing negative	LR− = (1 − sensitivity) / specificity

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Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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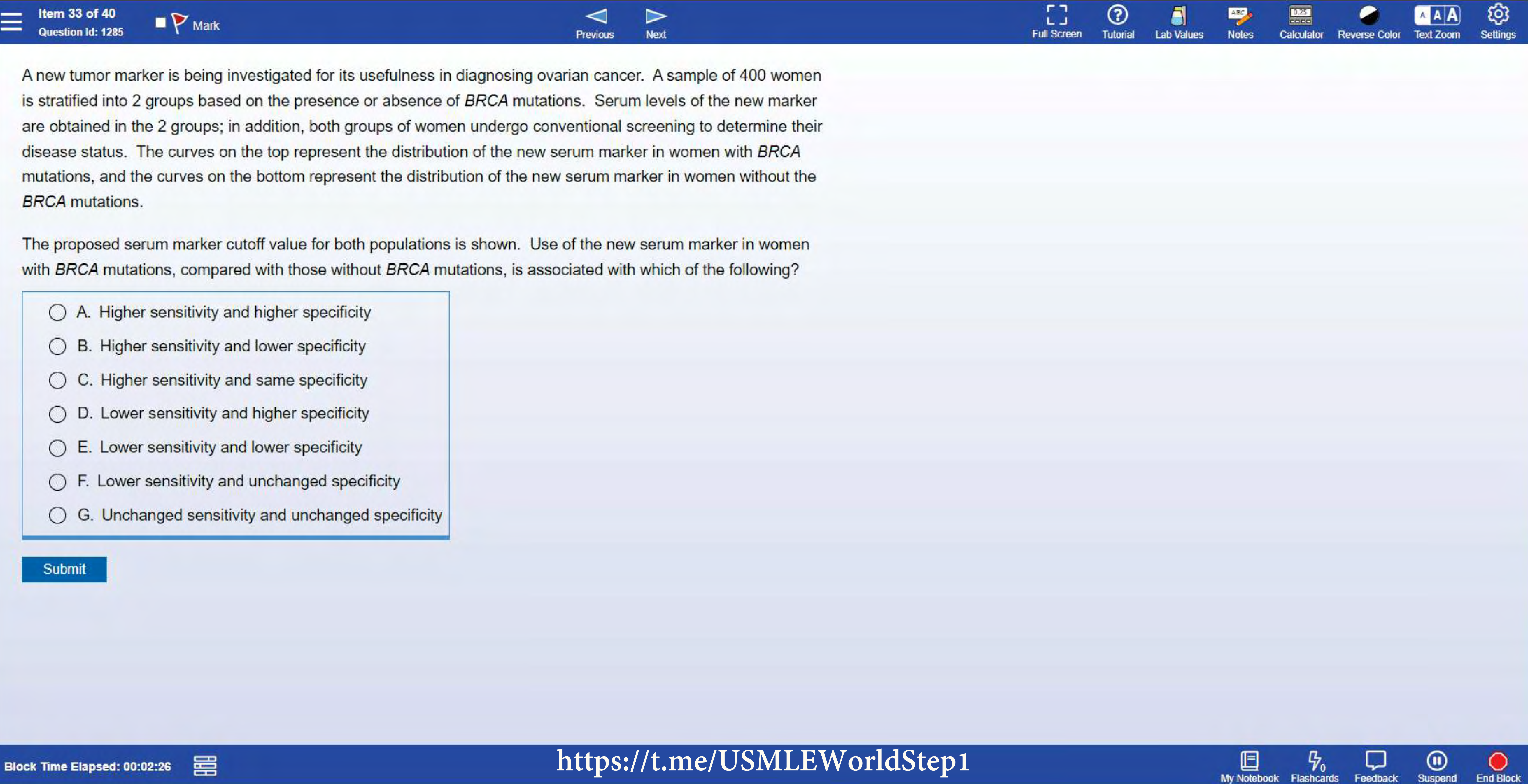
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A new tumor marker is being investigated for its usefulness in diagnosing ovarian cancer. A sample of 400 women is stratified into 2 groups based on the presence or absence of *BRCA* mutations. Serum levels of the new marker are obtained in the 2 groups; in addition, both groups of women undergo conventional screening to determine their disease status. The curves on the top represent the distribution of the new serum marker in women with *BRCA* mutations, and the curves on the bottom represent the distribution of the new serum marker in women without the *BRCA* mutations.

The proposed serum marker cutoff value for both populations is shown. Use of the new serum marker in women with *BRCA* mutations, compared with those without *BRCA* mutations, is associated with which of the following?

○ A. Higher sensitivity and higher specificity
○ B. Higher sensitivity and lower specificity
○ C. Higher sensitivity and same specificity
○ D. Lower sensitivity and higher specificity
○ E. Lower sensitivity and lower specificity
○ F. Lower sensitivity and unchanged specificity
○ G. Unchanged sensitivity and unchanged specificity

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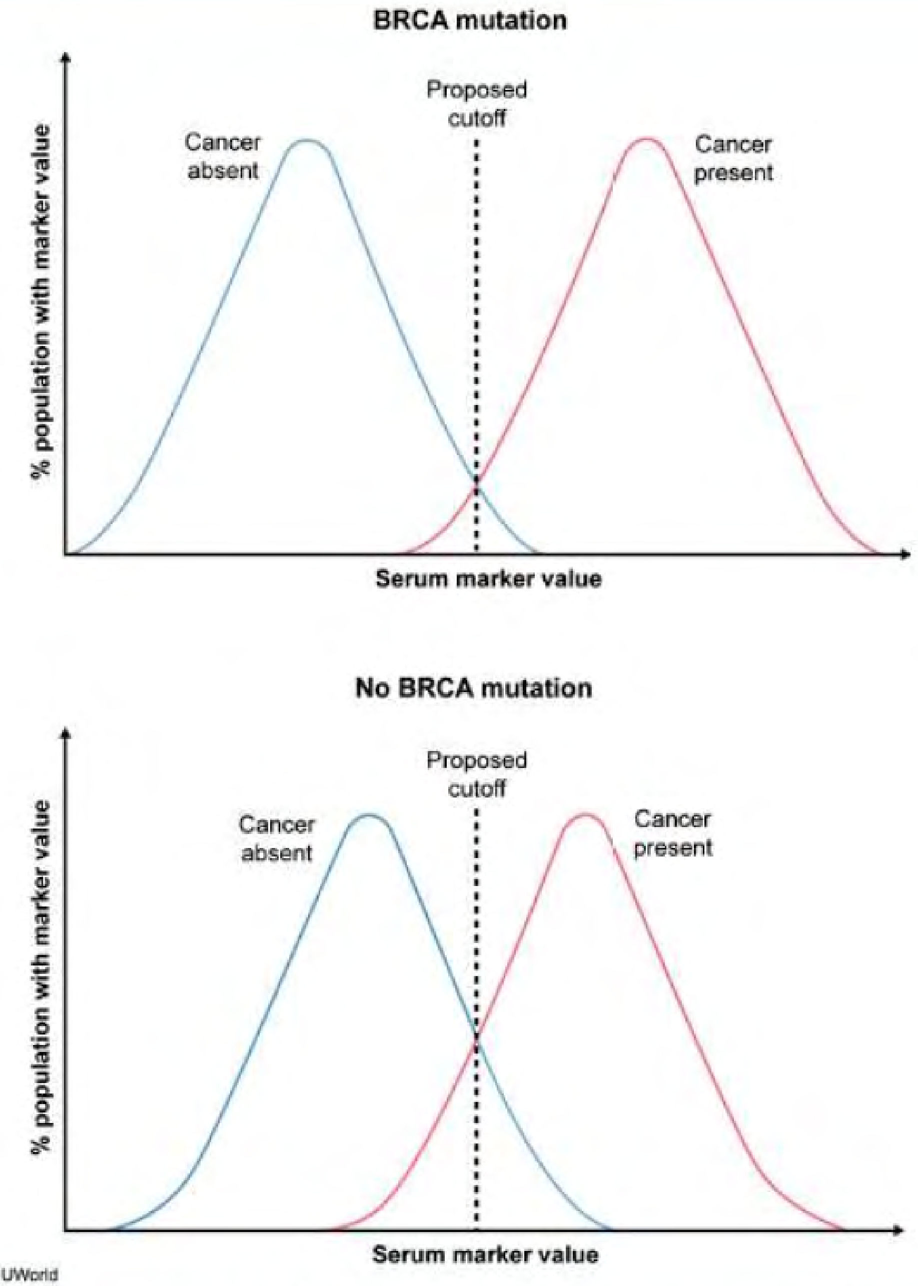

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with *BRCA* mutations, compared with those without *BRCA* mutations, is associated with which of the following?

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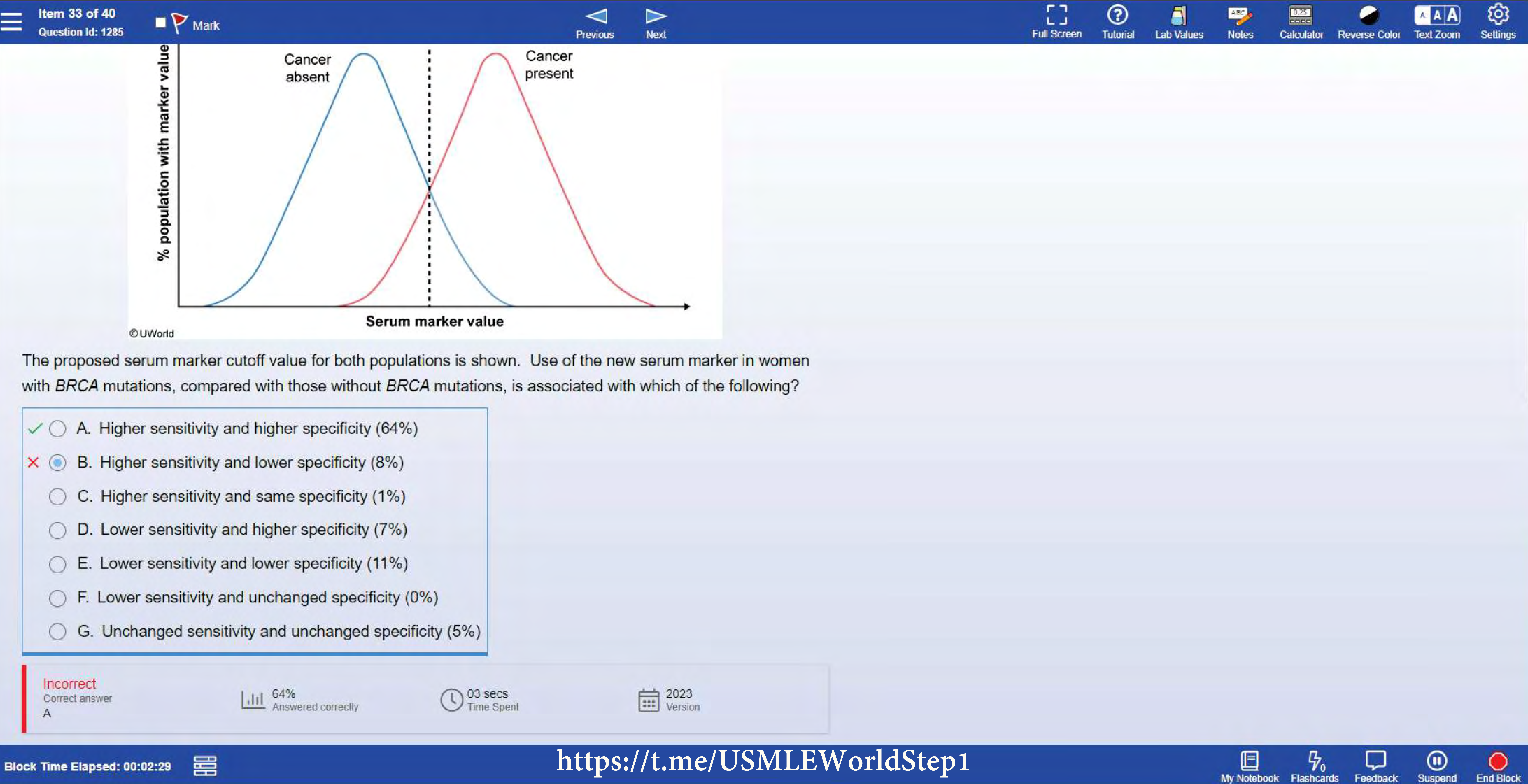
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% population with marker value
Cancer absent
Cancer present
Serum marker value
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The proposed serum marker cutoff value for both populations is shown. Use of the new serum marker in women with *BRCA* mutations, compared with those without *BRCA* mutations, is associated with which of the following?

- ✓ ○ A. Higher sensitivity and higher specificity (64%)
- ✗ ● B. Higher sensitivity and lower specificity (8%)
- ○ C. Higher sensitivity and same specificity (1%)
- ○ D. Lower sensitivity and higher specificity (7%)
- ○ E. Lower sensitivity and lower specificity (11%)
- ○ F. Lower sensitivity and unchanged specificity (0%)
- ○ G. Unchanged sensitivity and unchanged specificity (5%)

Incorrect
Correct answer
A

64%
Answered correctly

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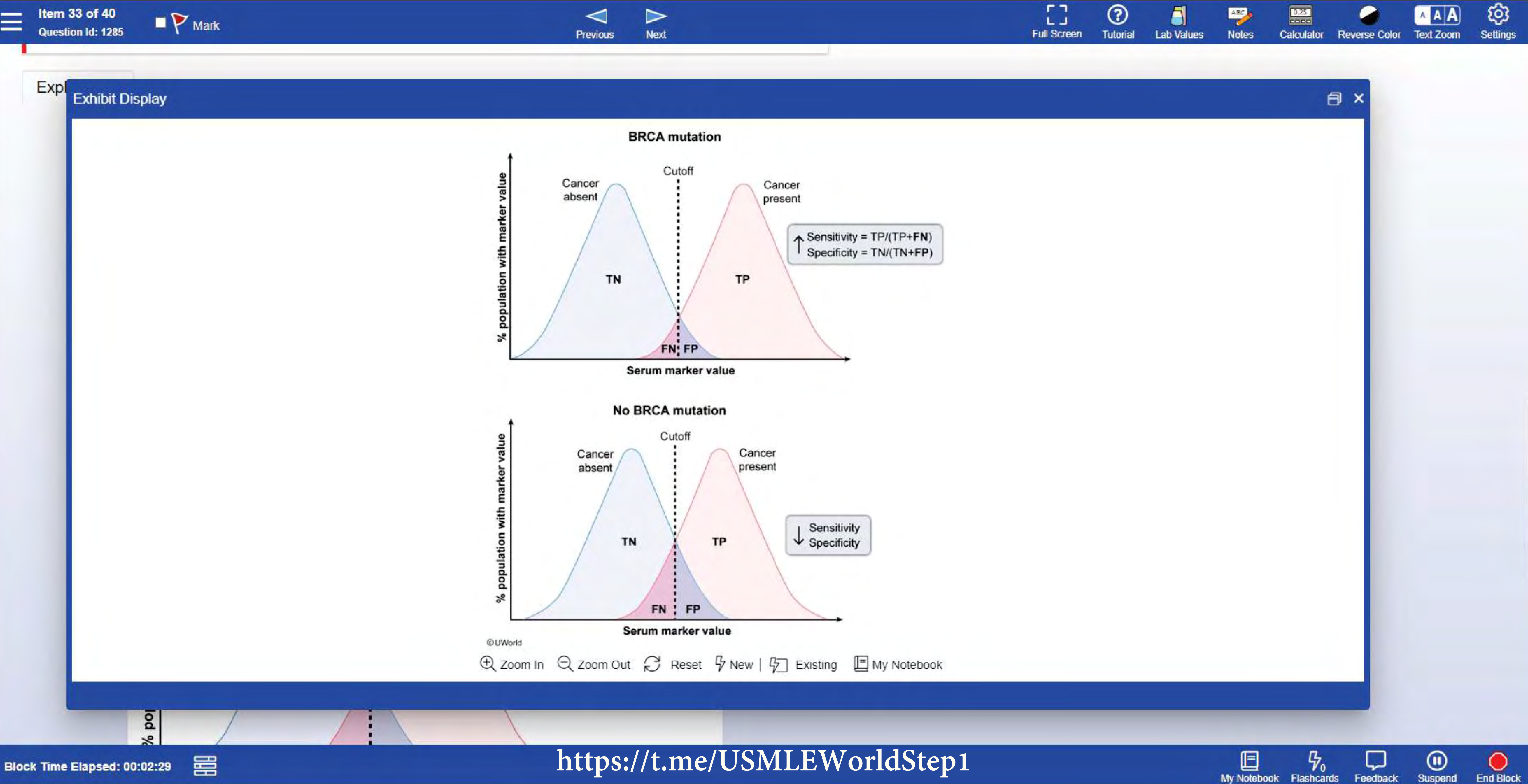
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BRCA mutation

% population with marker value
Cancer absent
Cutoff
Cancer present
TN
TP
FN
FP
Serum marker value

↑ Sensitivity = TP/(TP+**FN**)
Specificity = TN/(TN+**FP**)

No BRCA mutation

% population with marker value
Cancer absent
Cutoff
Cancer present
TN
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FN
FP
Serum marker value

↓ Sensitivity
Specificity

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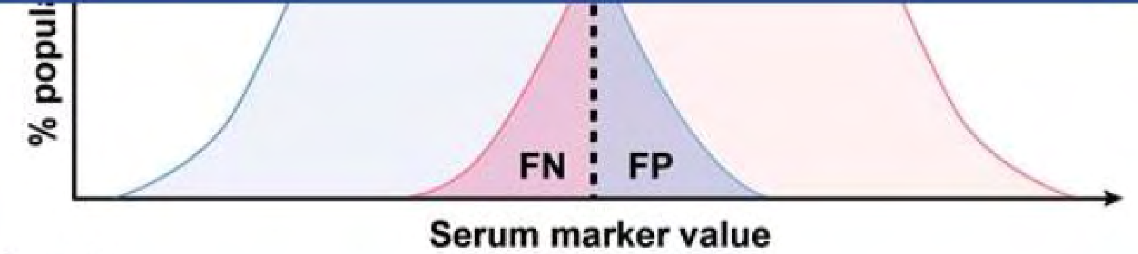

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The cutoff value of a quantitative diagnostic test determines whether a given result is interpreted as positive or negative. When there is **overlap between** the serum values of the **healthy and diseased populations**, a cutoff value that correctly categorizes all individuals in both populations cannot be chosen. This **limits the sensitivity and specificity** of the test due to the presence of false positive (FP) and/or false negative (FN) individuals.

Sensitivity represents the ability of a test to correctly identify those with a given disease. It is calculated as the number of patients correctly testing positive (TP) divided by the total number of patients with the disease (TP / [TP + FN]). Specificity represents the ability of a test to correctly identify those without a given disease. It is calculated as the number of patients correctly testing negative (TN) divided by the total number of patients without the disease (TN / [TN + FP]).

In this case, values of the serum marker in women with *BRCA* mutations show **decreased overlap** between the healthy and diseased curves of women with *BRCA* mutations (curves on the top) compared with women without *BRCA* mutations (curves on the bottom). The corresponding decrease in the number of FPs and FNs means the new serum marker has **higher sensitivity and specificity** (ie, better performance) in women with *BRCA* mutations.

Educational objective:

The degree of overlap between the healthy and the diseased population curves limits the maximum combined sensitivity and specificity of a quantitative diagnostic test. The degree to which sensitivity or specificity is affected depends on the chosen cutoff value.

Biostatistics	Biostatistics & Epidemiology	Sensitivity and specificity
Subject	System	Topic

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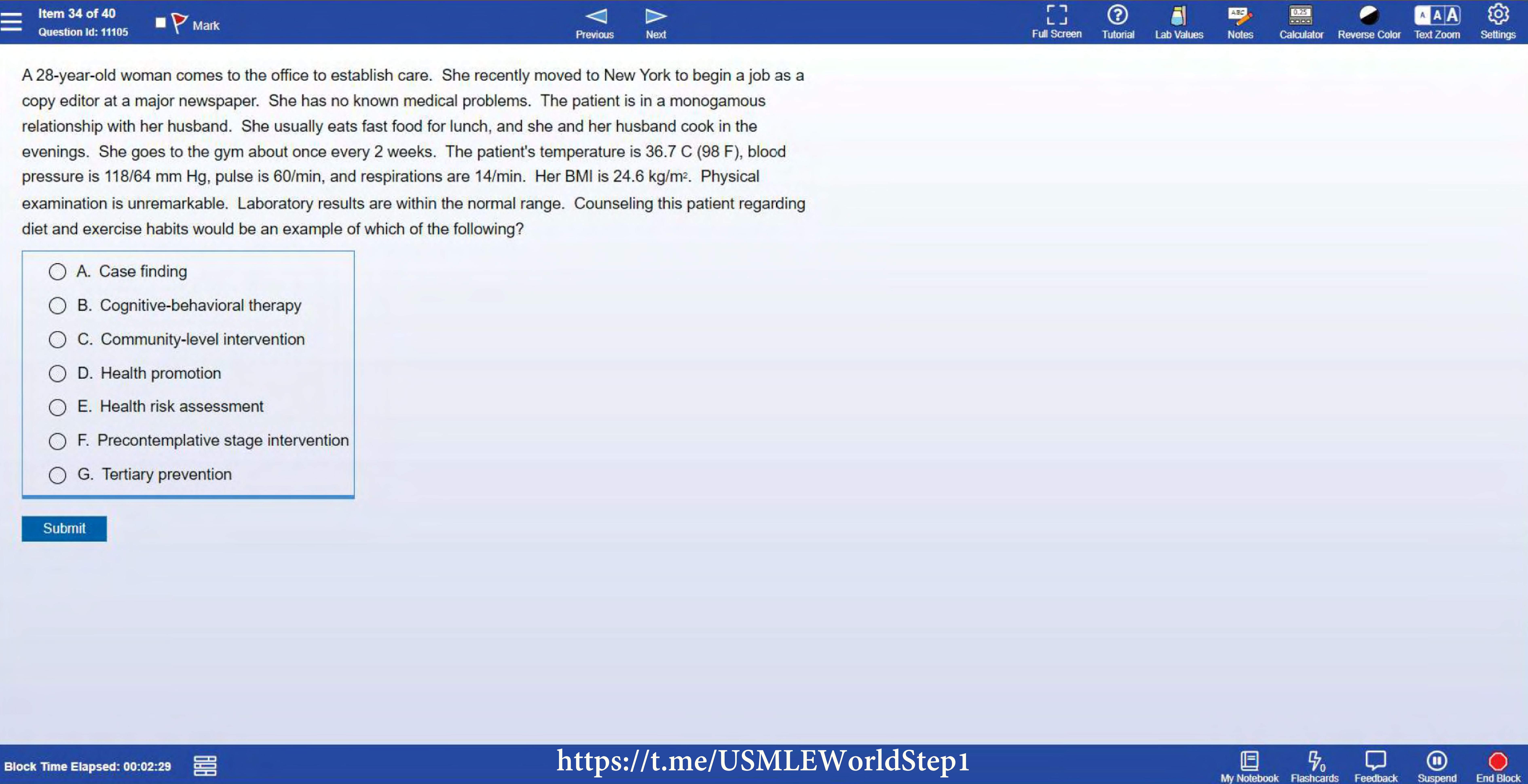

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A 28-year-old woman comes to the office to establish care. She recently moved to New York to begin a job as a copy editor at a major newspaper. She has no known medical problems. The patient is in a monogamous relationship with her husband. She usually eats fast food for lunch, and she and her husband cook in the evenings. She goes to the gym about once every 2 weeks. The patient's temperature is 36.7 C (98 F), blood pressure is 118/64 mm Hg, pulse is 60/min, and respirations are 14/min. Her BMI is 24.6 kg/m^2. Physical examination is unremarkable. Laboratory results are within the normal range. Counseling this patient regarding diet and exercise habits would be an example of which of the following?

○ A. Case finding

○ B. Cognitive-behavioral therapy

○ C. Community-level intervention

○ D. Health promotion

○ E. Health risk assessment

○ F. Precontemplative stage intervention

○ G. Tertiary prevention

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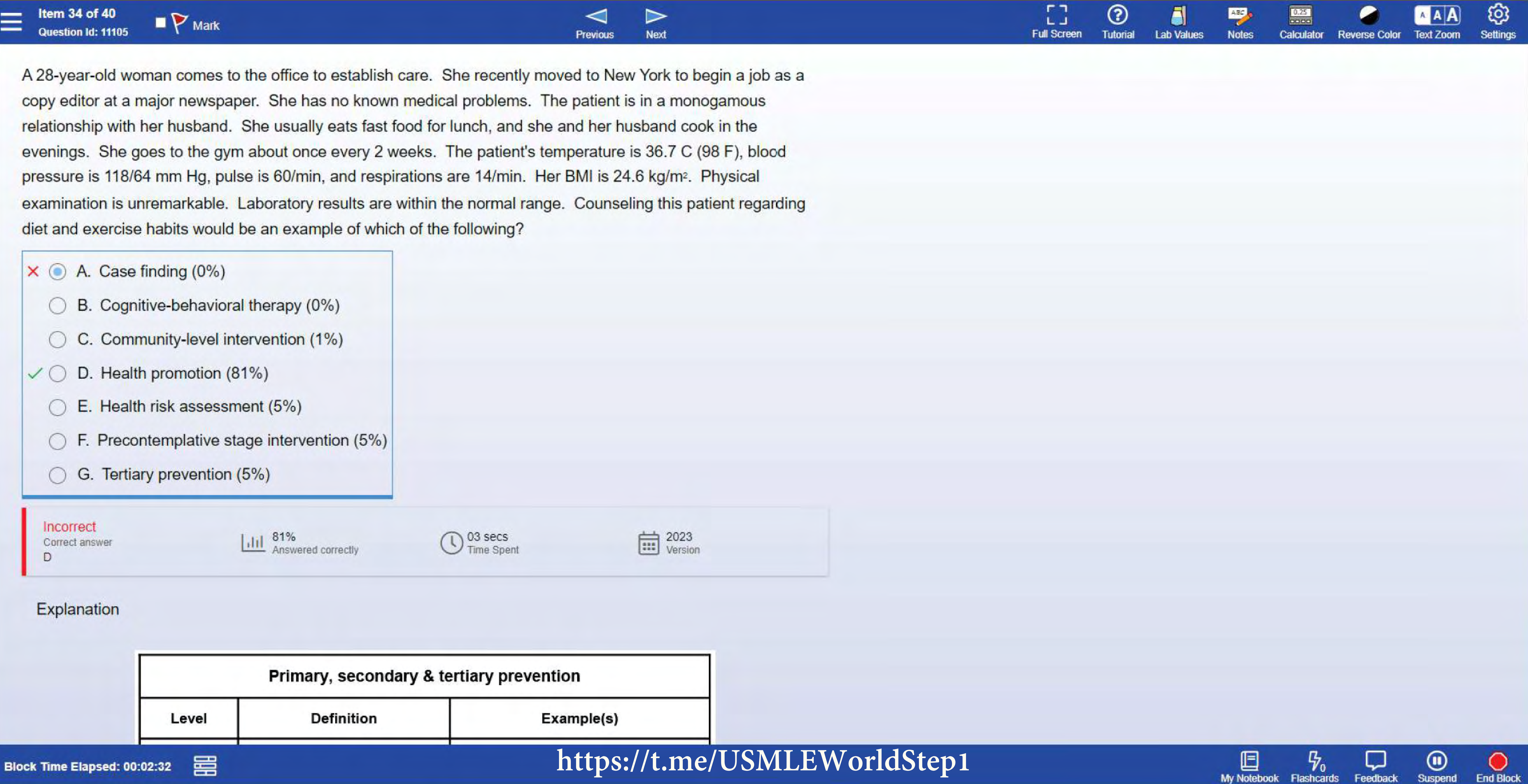
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✗ ● A. Case finding (0%)
○ B. Cognitive-behavioral therapy (0%)
○ C. Community-level intervention (1%)
✓ ○ D. Health promotion (81%)
○ E. Health risk assessment (5%)
○ F. Precontemplative stage intervention (5%)
○ G. Tertiary prevention (5%)

Incorrect
Correct answer
D

81%
Answered correctly

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Explanation

Primary, secondary & tertiary prevention

Level	Definition	Example(s)

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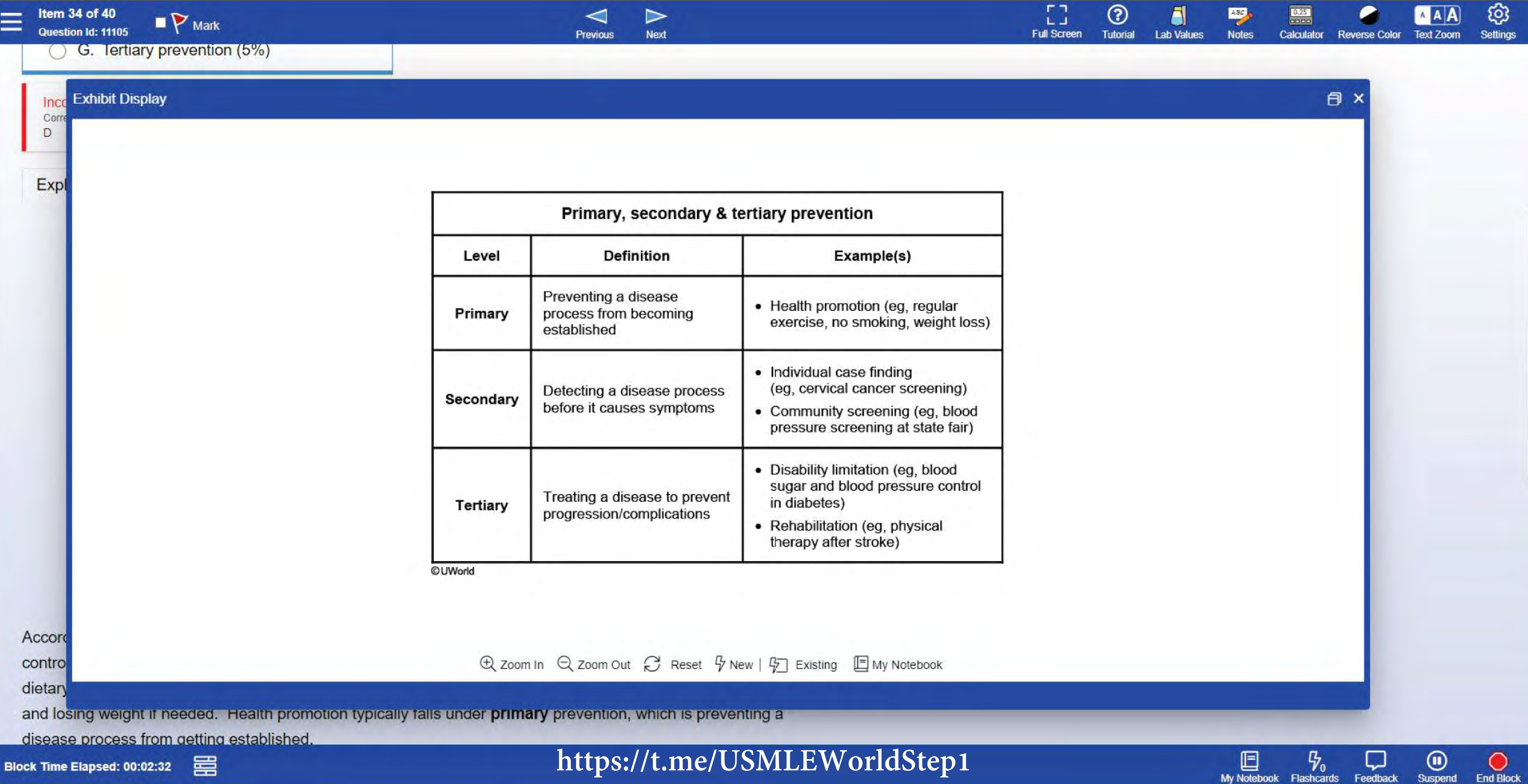
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○ G. Tertiary prevention (5%)

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Primary, secondary & tertiary prevention		
Level	**Definition**	**Example(s)**
Primary	Preventing a disease process from becoming established	• Health promotion (eg, regular exercise, no smoking, weight loss)
Secondary	Detecting a disease process before it causes symptoms	• Individual case finding (eg, cervical cancer screening) • Community screening (eg, blood pressure screening at state fair)
Tertiary	Treating a disease to prevent progression/complications	• Disability limitation (eg, blood sugar and blood pressure control in diabetes) • Rehabilitation (eg, physical therapy after stroke)

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and losing weight if needed. Health promotion typically falls under **primary** prevention, which is preventing a disease process from getting established.

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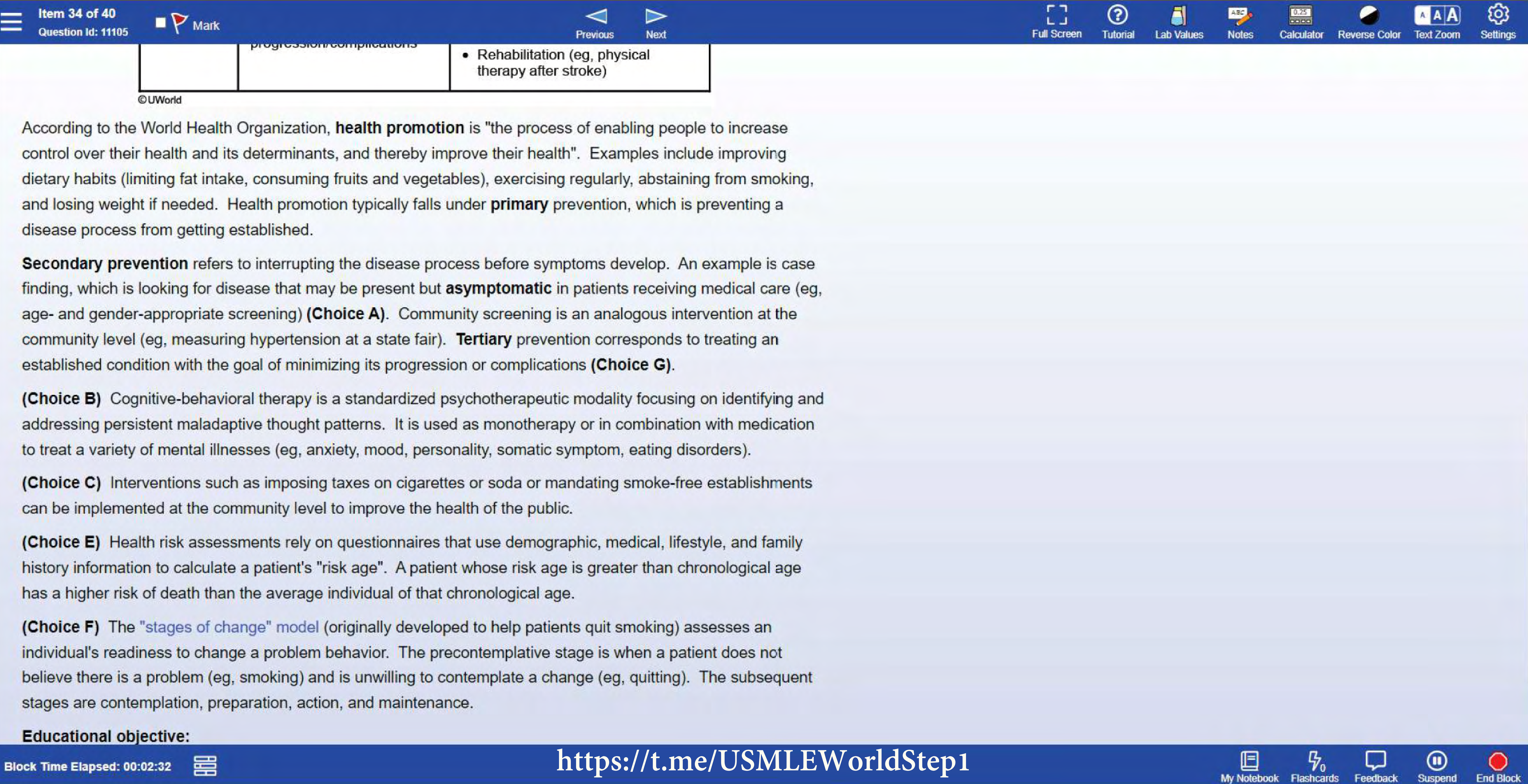

	progression/complications	• Rehabilitation (eg, physical therapy after stroke)

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According to the World Health Organization, **health promotion** is "the process of enabling people to increase control over their health and its determinants, and thereby improve their health". Examples include improving dietary habits (limiting fat intake, consuming fruits and vegetables), exercising regularly, abstaining from smoking, and losing weight if needed. Health promotion typically falls under **primary** prevention, which is preventing a disease process from getting established.

Secondary prevention refers to interrupting the disease process before symptoms develop. An example is case finding, which is looking for disease that may be present but **asymptomatic** in patients receiving medical care (eg, age- and gender-appropriate screening) **(Choice A)**. Community screening is an analogous intervention at the community level (eg, measuring hypertension at a state fair). **Tertiary** prevention corresponds to treating an established condition with the goal of minimizing its progression or complications **(Choice G)**.

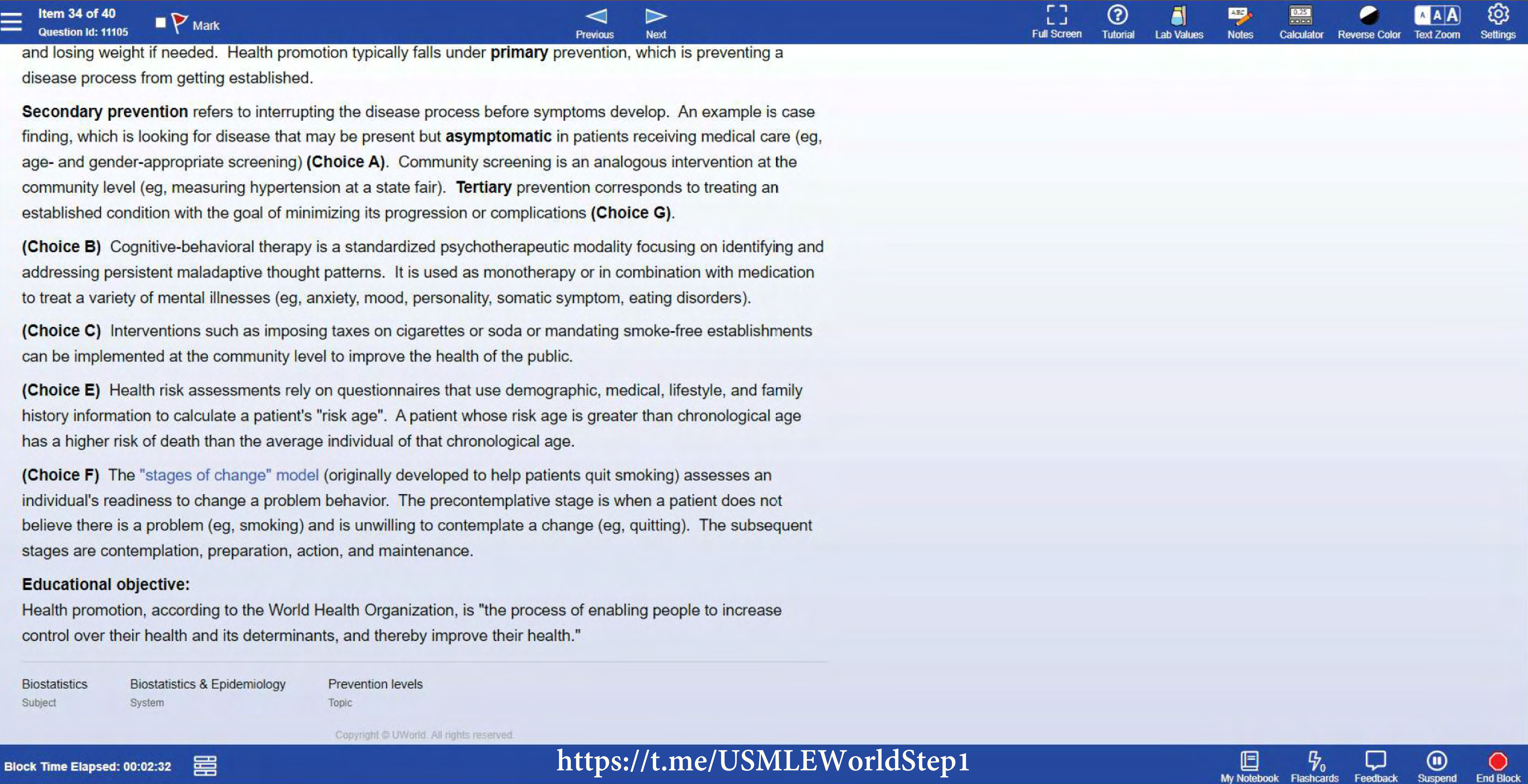
(Choice B) Cognitive-behavioral therapy is a standardized psychotherapeutic modality focusing on identifying and addressing persistent maladaptive thought patterns. It is used as monotherapy or in combination with medication to treat a variety of mental illnesses (eg, anxiety, mood, personality, somatic symptom, eating disorders).

(Choice C) Interventions such as imposing taxes on cigarettes or soda or mandating smoke-free establishments can be implemented at the community level to improve the health of the public.

(Choice E) Health risk assessments rely on questionnaires that use demographic, medical, lifestyle, and family history information to calculate a patient's "risk age". A patient whose risk age is greater than chronological age has a higher risk of death than the average individual of that chronological age.

(Choice F) The "stages of change" model (originally developed to help patients quit smoking) assesses an individual's readiness to change a problem behavior. The precontemplative stage is when a patient does not believe there is a problem (eg, smoking) and is unwilling to contemplate a change (eg, quitting). The subsequent stages are contemplation, preparation, action, and maintenance.

Educational objective:



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and losing weight if needed. Health promotion typically falls under **primary** prevention, which is preventing a disease process from getting established.

Secondary prevention refers to interrupting the disease process before symptoms develop. An example is case finding, which is looking for disease that may be present but **asymptomatic** in patients receiving medical care (eg, age- and gender-appropriate screening) **(Choice A)**. Community screening is an analogous intervention at the community level (eg, measuring hypertension at a state fair). **Tertiary** prevention corresponds to treating an established condition with the goal of minimizing its progression or complications **(Choice G)**.

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Educational objective:

Health promotion, according to the World Health Organization, is "the process of enabling people to increase control over their health and its determinants, and thereby improve their health."

Biostatistics	Biostatistics & Epidemiology	Prevention levels
Subject	System	Topic

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and losing weight if needed. Health promotion typically falls under **primary** prevention, which is preventing a disease process from getting established.

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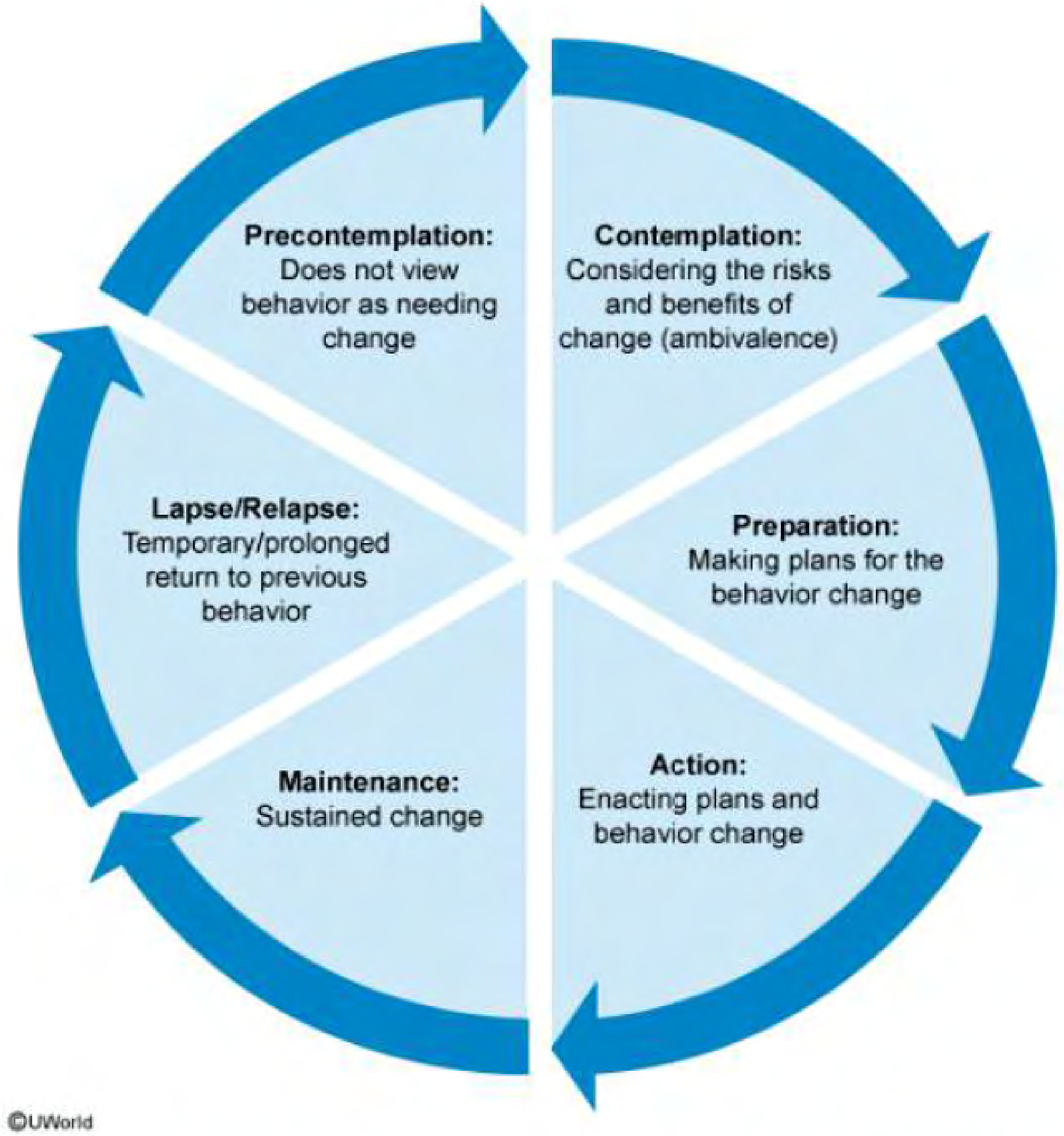
Stages of behavior change



Precontemplation: Does not view behavior as needing change

Contemplation: Considering the risks and benefits of change (ambivalence)

Preparation: Making plans for the behavior change

Action: Enacting plans and behavior change

Maintenance: Sustained change

Lapse/Relapse: Temporary/prolonged return to previous behavior

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A prospective study evaluates the relationship between regular antioxidant supplement use (vitamins C and E) and the risk of stroke in healthy and physically active men age 40-60. The study compares the risk of stroke among men who consumed antioxidant supplements for ≥5 years and among men who consumed antioxidant supplements for <5 years, as compared to a reference group of men who never consumed antioxidant supplements. According to the study results, men who consumed antioxidant supplements for <5 years and men who consumed antioxidant supplements for ≥5 years have stroke relative risks of 0.95 ($p = 0.45$) and 0.75 ($p < 0.01$), respectively, when compared to the reference group. The results of the study were adjusted to account for baseline differences related to healthy behaviors and overall health. Which of the following factors most likely explains why the relative risk of stroke is lower with longer antioxidant use?

○ A. Accumulation effect
○ B. Lead-time bias
○ C. Observer bias
○ D. Rare disease assumption
○ E. Selection bias

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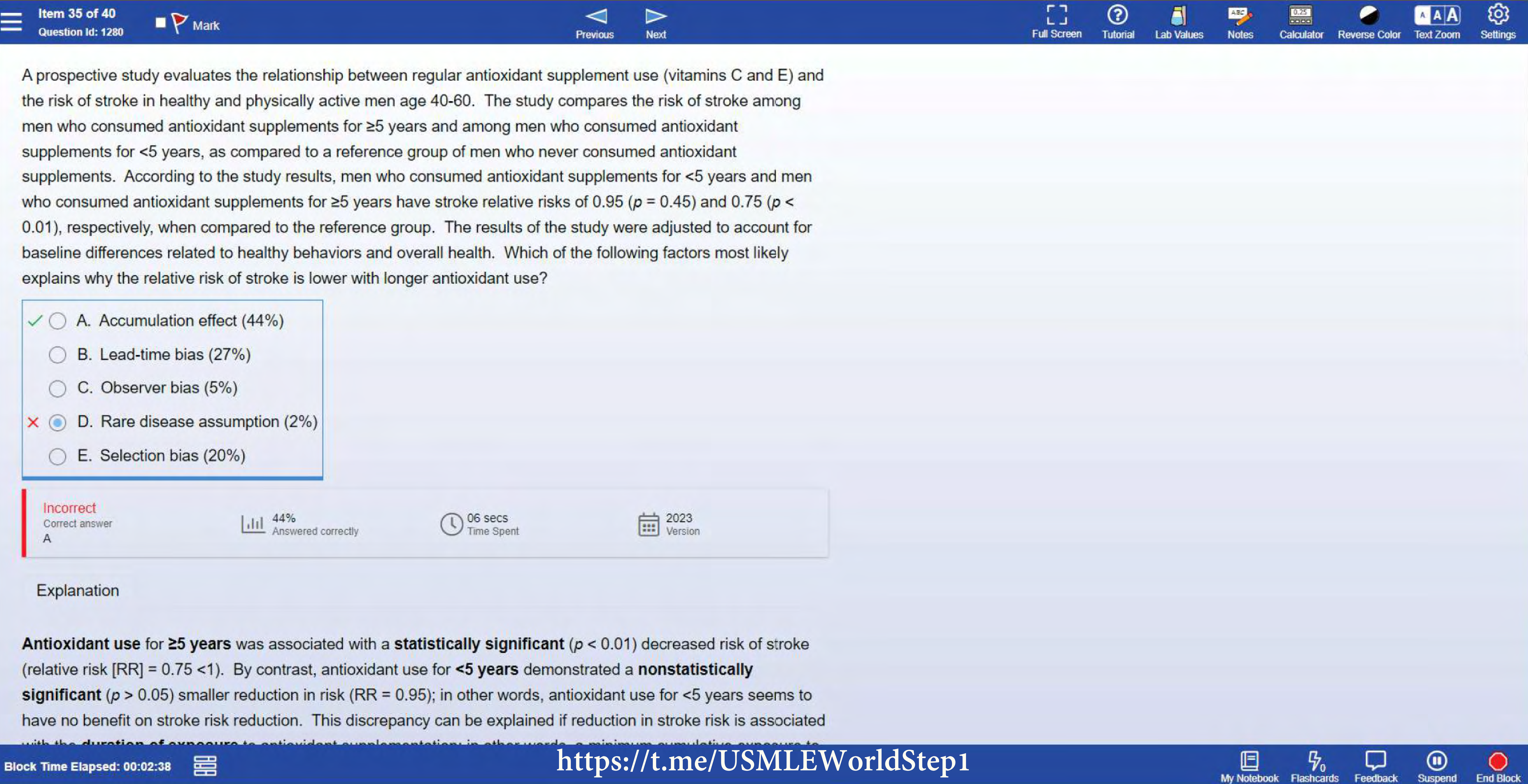
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A prospective study evaluates the relationship between regular antioxidant supplement use (vitamins C and E) and the risk of stroke in healthy and physically active men age 40-60. The study compares the risk of stroke among men who consumed antioxidant supplements for ≥5 years and among men who consumed antioxidant supplements for <5 years, as compared to a reference group of men who never consumed antioxidant supplements. According to the study results, men who consumed antioxidant supplements for <5 years and men who consumed antioxidant supplements for ≥5 years have stroke relative risks of 0.95 ($p = 0.45$) and 0.75 ($p < 0.01$), respectively, when compared to the reference group. The results of the study were adjusted to account for baseline differences related to healthy behaviors and overall health. Which of the following factors most likely explains why the relative risk of stroke is lower with longer antioxidant use?

✓ ○ A. Accumulation effect (44%)
○ B. Lead-time bias (27%)
○ C. Observer bias (5%)
✗ ● D. Rare disease assumption (2%)
○ E. Selection bias (20%)

Incorrect
Correct answer
A

44%
Answered correctly

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Explanation

Antioxidant use for **≥5 years** was associated with a **statistically significant** ($p < 0.01$) decreased risk of stroke (relative risk [RR] = 0.75 <1). By contrast, antioxidant use for **<5 years** demonstrated a **nonstatistically significant** ($p > 0.05$) smaller reduction in risk (RR = 0.95); in other words, antioxidant use for <5 years seems to have no benefit on stroke risk reduction. This discrepancy can be explained if reduction in stroke risk is associated

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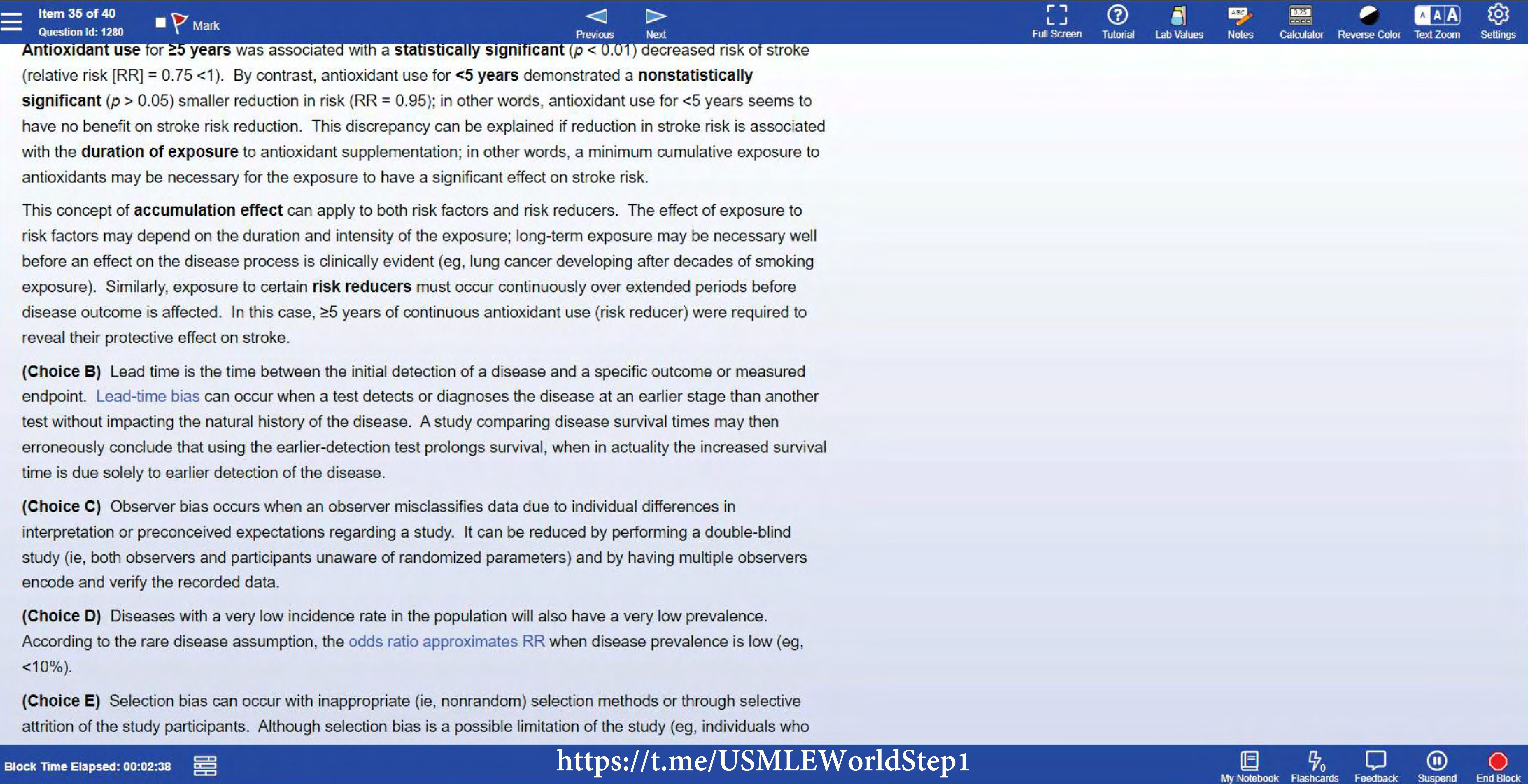

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This concept of **accumulation effect** can apply to both risk factors and risk reducers. The effect of exposure to risk factors may depend on the duration and intensity of the exposure; long-term exposure may be necessary well before an effect on the disease process is clinically evident (eg, lung cancer developing after decades of smoking exposure). Similarly, exposure to certain **risk reducers** must occur continuously over extended periods before disease outcome is affected. In this case, ≥5 years of continuous antioxidant use (risk reducer) were required to reveal their protective effect on stroke.

(Choice B) Lead time is the time between the initial detection of a disease and a specific outcome or measured endpoint. Lead-time bias can occur when a test detects or diagnoses the disease at an earlier stage than another test without impacting the natural history of the disease. A study comparing disease survival times may then erroneously conclude that using the earlier-detection test prolongs survival, when in actuality the increased survival time is due solely to earlier detection of the disease.

(Choice C) Observer bias occurs when an observer misclassifies data due to individual differences in interpretation or preconceived expectations regarding a study. It can be reduced by performing a double-blind study (ie, both observers and participants unaware of randomized parameters) and by having multiple observers encode and verify the recorded data.

(Choice D) Diseases with a very low incidence rate in the population will also have a very low prevalence. According to the rare disease assumption, the odds ratio approximates RR when disease prevalence is low (eg, <10%).

(Choice E) Selection bias can occur with inappropriate (ie, nonrandom) selection methods or through selective attrition of the study participants. Although selection bias is a possible limitation of the study (eg, individuals who

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(Choice B) Lead time is the time between the initial detection of a disease and a specific outcome or measured endpoint. Lead-time bias can occur when a test detects or diagnoses the disease at an earlier stage than another test without impacting the natural history of the disease. A study comparing disease survival times may then erroneously conclude that using the earlier-detection test prolongs survival, when in actuality the increased survival time is due solely to earlier detection of the disease.

(Choice C) Observer bias occurs when an observer misclassifies data due to individual differences in interpretation or preconceived expectations regarding a study. It can be reduced by performing a double-blind study (ie, both observers and participants unaware of randomized parameters) and by having multiple observers encode and verify the recorded data.

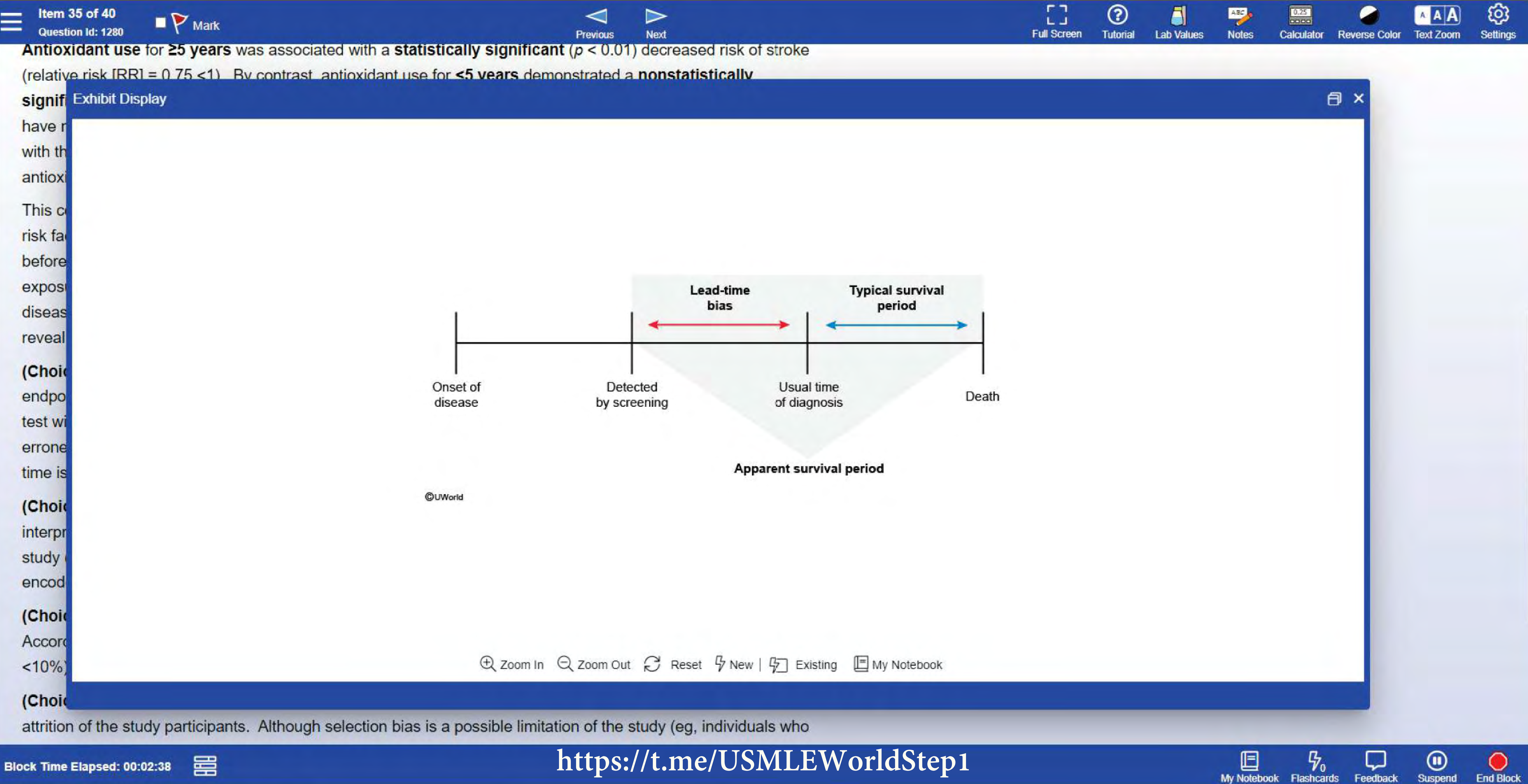
(Choice D) Diseases with a very low incidence rate in the population will also have a very low prevalence. According to the rare disease assumption, the odds ratio approximates RR when disease prevalence is low (eg, <10%).

(Choice E) Selection bias can occur with inappropriate (ie, nonrandom) selection methods or through selective attrition of the study participants. Although selection bias is a possible limitation of the study (eg, individuals who take vitamins daily may be more likely to be already healthy), the fact that the study was limited to healthy, physically active men and that it adjusted for baseline differences should considerably reduce the effect of this potential bias.

Educational objective:

The concept of accumulation effect can be applied to disease pathogenesis and exposure to risk modifiers. Cumulative exposure to a risk factor or risk reducer must sometimes occur for prolonged periods before a clinically significant effect is detected.

Biostatistics	Biostatistics & Epidemiology	Risk
Subject	System	Topic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Lead-time bias
Typical survival period
Onset of disease
Detected by screening
Usual time of diagnosis
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Apparent survival period
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Antioxidant use for **≥5 years** was associated with a **statistically significant** ($p < 0.01$) decreased risk of stroke (relative risk [RR] = 0.75 <1). By contrast, antioxidant use for **<5 years** demonstrated a **nonstatistically signifi**

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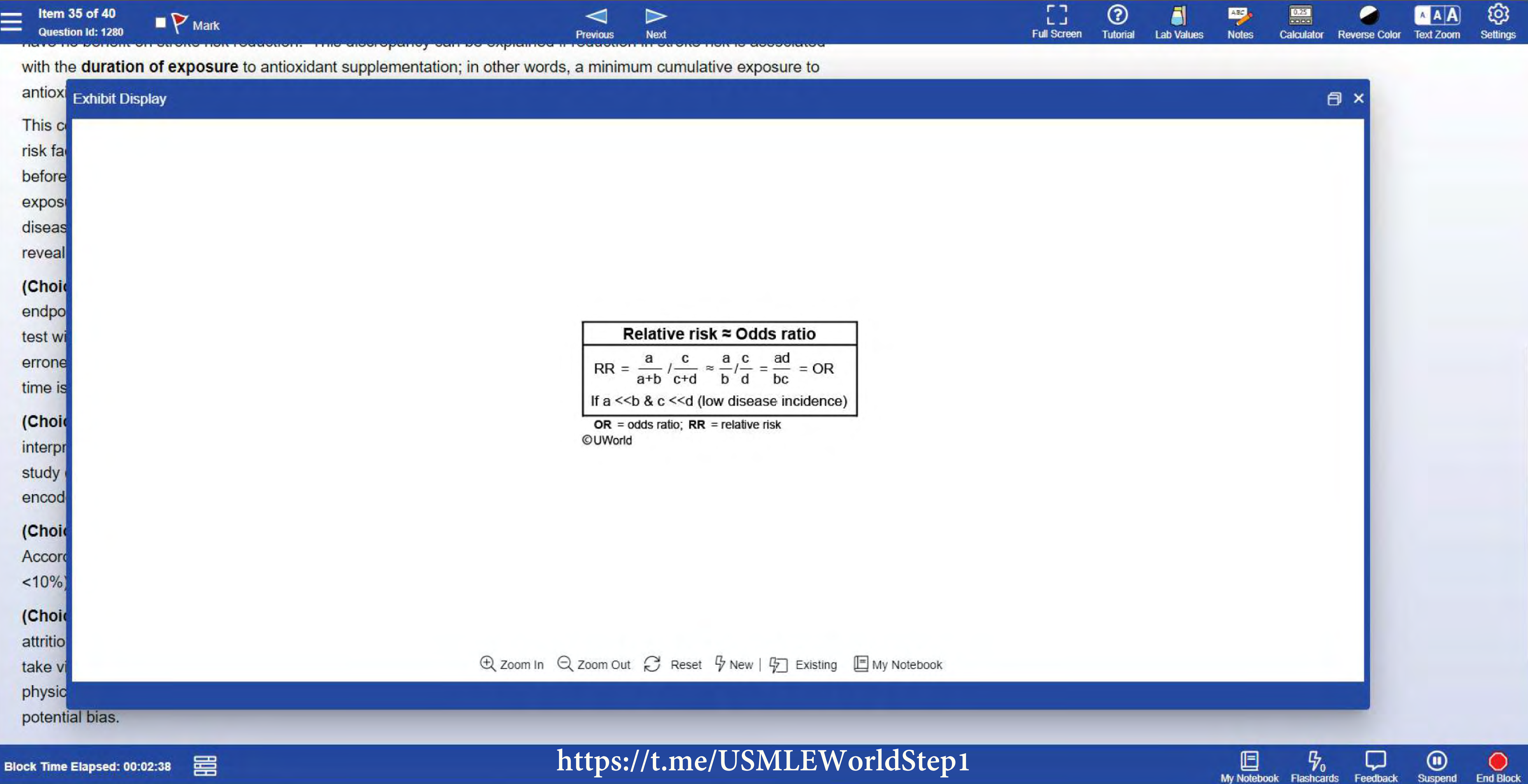
attrition of the study participants. Although selection bias is a possible limitation of the study (eg, individuals who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with the **duration of exposure** to antioxidant supplementation; in other words, a minimum cumulative exposure to

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Relative risk ≈ Odds ratio

$$RR = \frac{a}{a+b} / \frac{c}{c+d} \approx \frac{a}{b} / \frac{c}{d} = \frac{ad}{bc} = OR$$

If a <<b & c <<d (low disease incidence)

OR = odds ratio; **RR** = relative risk

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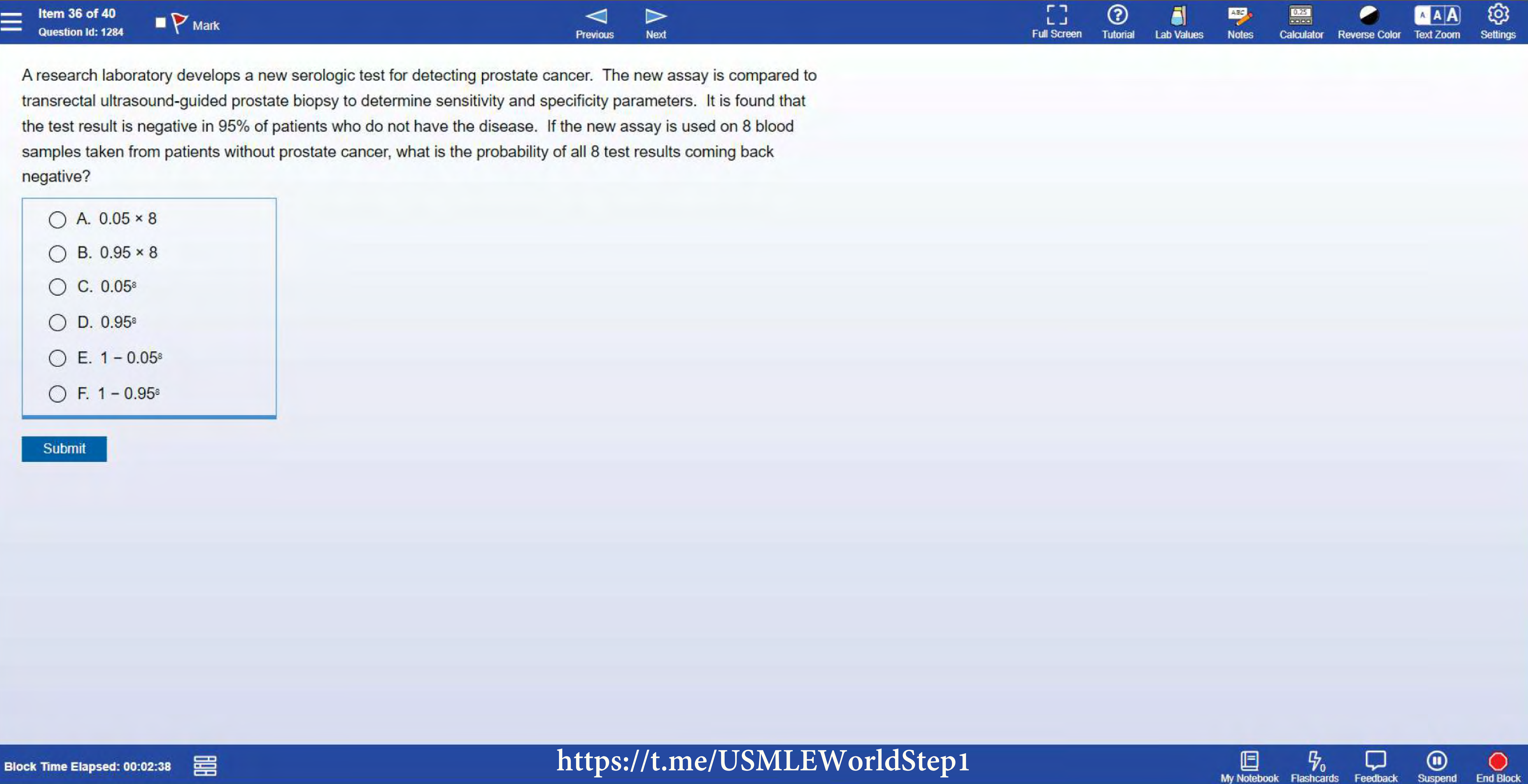
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A research laboratory develops a new serologic test for detecting prostate cancer. The new assay is compared to transrectal ultrasound-guided prostate biopsy to determine sensitivity and specificity parameters. It is found that the test result is negative in 95% of patients who do not have the disease. If the new assay is used on 8 blood samples taken from patients without prostate cancer, what is the probability of all 8 test results coming back negative?

○ A. 0.05 × 8
○ B. 0.95 × 8
○ C. 0.05^8
○ D. 0.95^8
○ E. $1 - 0.05^8$
○ F. $1 - 0.95^8$

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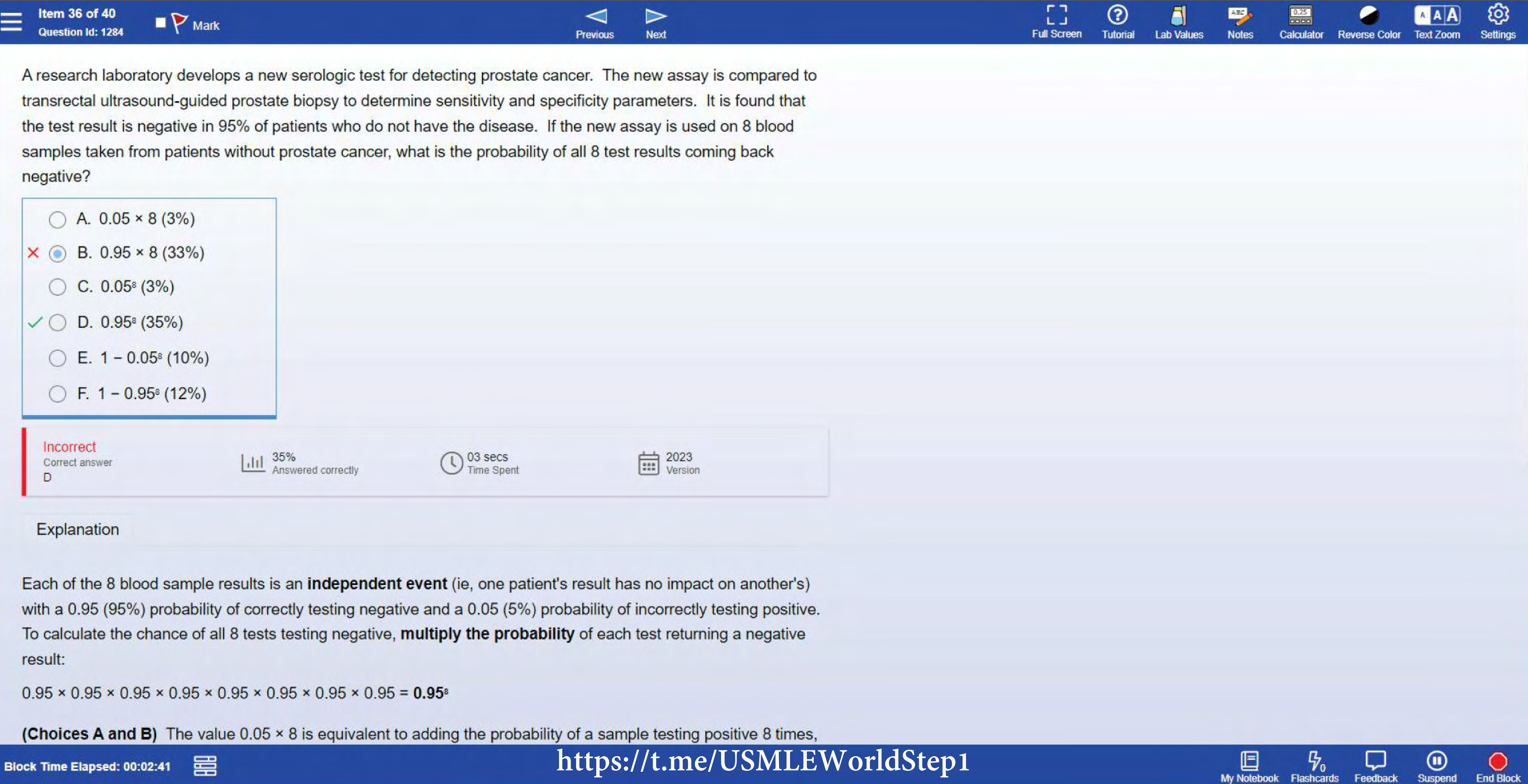
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A research laboratory develops a new serologic test for detecting prostate cancer. The new assay is compared to transrectal ultrasound-guided prostate biopsy to determine sensitivity and specificity parameters. It is found that the test result is negative in 95% of patients who do not have the disease. If the new assay is used on 8 blood samples taken from patients without prostate cancer, what is the probability of all 8 test results coming back negative?

○ A. 0.05 × 8 (3%)

✗ ● B. 0.95 × 8 (33%)

○ C. 0.05^8 (3%)

✓ ○ D. 0.95^8 (35%)

○ E. 1 – 0.05^8 (10%)

○ F. 1 – 0.95^8 (12%)

Incorrect
Correct answer
D

35%
Answered correctly

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Explanation

Each of the 8 blood sample results is an **independent event** (ie, one patient's result has no impact on another's) with a 0.95 (95%) probability of correctly testing negative and a 0.05 (5%) probability of incorrectly testing positive. To calculate the chance of all 8 tests testing negative, **multiply the probability** of each test returning a negative result:

$0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 = \mathbf{0.95^8}$

(Choices A and B) The value 0.05 × 8 is equivalent to adding the probability of a sample testing positive 8 times,

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Explanation

Each of the 8 blood sample results is an **independent event** (ie, one patient's result has no impact on another's) with a 0.95 (95%) probability of correctly testing negative and a 0.05 (5%) probability of incorrectly testing positive. To calculate the chance of all 8 tests testing negative, **multiply the probability** of each test returning a negative result:

$0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 = \mathbf{0.95^8}$

(Choices A and B) The value 0.05 × 8 is equivalent to adding the probability of a sample testing positive 8 times, and 0.95 × 8 is equivalent to adding the probability of a sample testing negative 8 times. However, the combined probability for a series of independent events is calculated using multiplication, not addition. For instance, when flipping a coin twice the probability of getting 2 heads in a row is not 0.5 + 0.5 = 0.5 × 2 = 1 (100%) but rather 0.5 × 0.5 = 0.25 (25%).

(Choice C) The probability of all 8 samples incorrectly testing positive is given by 0.05^8.

(Choices E and F) Overall, 2 outcomes are possible: either all 8 samples will return the same test result or at least 1 sample will test differently. Because the total probability must add up to 1 (100%) and the probability that all 8 samples will return negative is given by 0.95^8, the probability of at least 1 sample testing positive is $1 - 0.95^8$. Conversely, the probability that all 8 samples will return positive is 0.05^8 while the probability of at least 1 sample testing negative is $1 - 0.05^8$.

Educational objective:

If events are independent, the probability that all events will turn out the same is the product of the separate probabilities for each event. The probability of at least 1 event turning out differently is given as 1 - P(all events being the same).

Biostatistics	Biostatistics & Epidemiology	Probability theory
Subject	System	Topic

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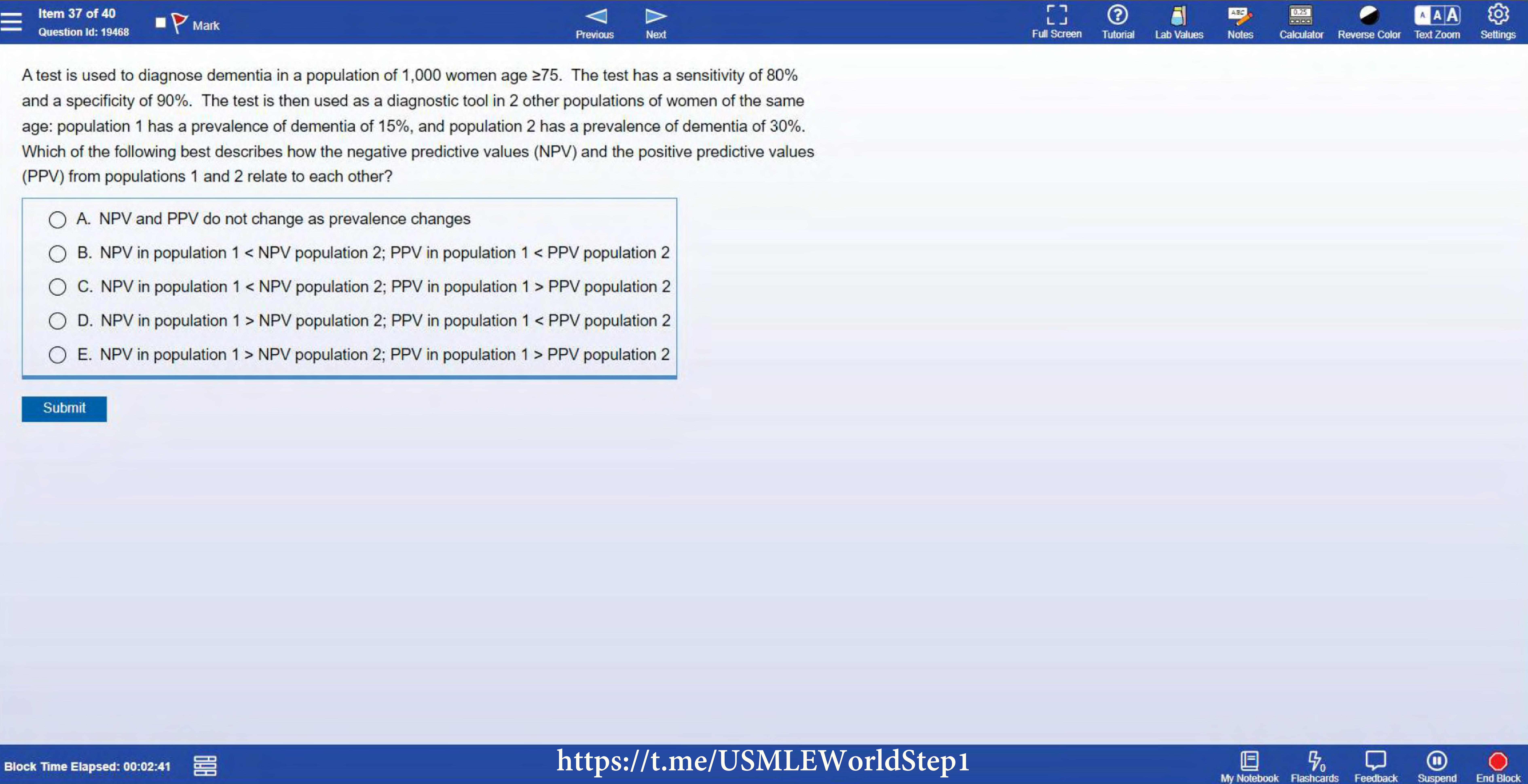
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A test is used to diagnose dementia in a population of 1,000 women age ≥75. The test has a sensitivity of 80% and a specificity of 90%. The test is then used as a diagnostic tool in 2 other populations of women of the same age: population 1 has a prevalence of dementia of 15%, and population 2 has a prevalence of dementia of 30%. Which of the following best describes how the negative predictive values (NPV) and the positive predictive values (PPV) from populations 1 and 2 relate to each other?

○ A. NPV and PPV do not change as prevalence changes
○ B. NPV in population 1 < NPV population 2; PPV in population 1 < PPV population 2
○ C. NPV in population 1 < NPV population 2; PPV in population 1 > PPV population 2
○ D. NPV in population 1 > NPV population 2; PPV in population 1 < PPV population 2
○ E. NPV in population 1 > NPV population 2; PPV in population 1 > PPV population 2

A test is used to diagnose dementia in a population of 1,000 women age ≥75. The test has a sensitivity of 80% and a specificity of 90%. The test is then used as a diagnostic tool in 2 other populations of women of the same age: population 1 has a prevalence of dementia of 15%, and population 2 has a prevalence of dementia of 30%. Which of the following best describes how the negative predictive values (NPV) and the positive predictive values (PPV) from populations 1 and 2 relate to each other?

- ○ A. NPV and PPV do not change as prevalence changes (7%)
- ✕ ● B. NPV in population 1 < NPV population 2; PPV in population 1 < PPV population 2 (7%)
- ○ C. NPV in population 1 < NPV population 2; PPV in population 1 > PPV population 2 (7%)
- ✓ ○ D. NPV in population 1 > NPV population 2; PPV in population 1 < PPV population 2 (76%)
- ○ E. NPV in population 1 > NPV population 2; PPV in population 1 > PPV population 2 (1%)

Incorrect
Correct answer
D

76%
Answered correctly

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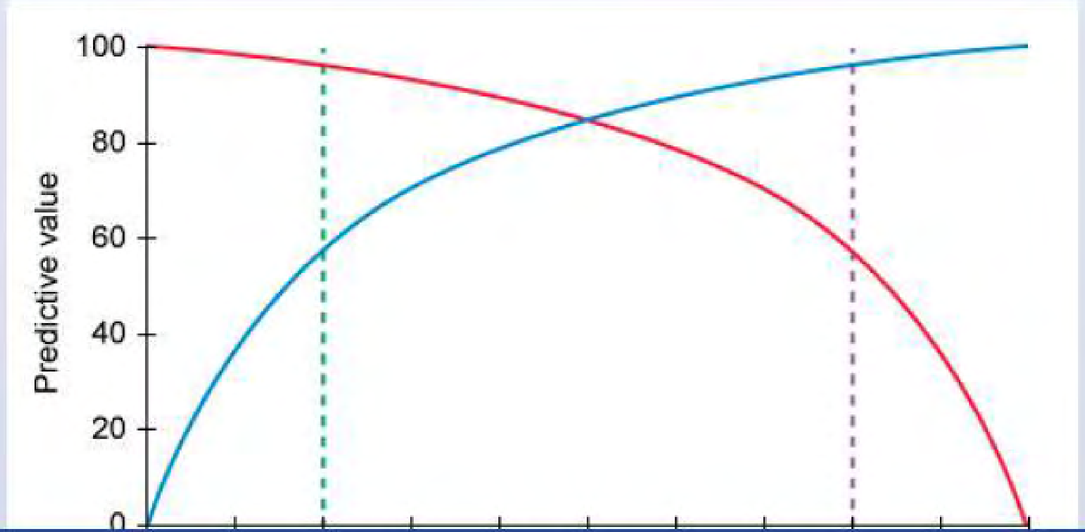
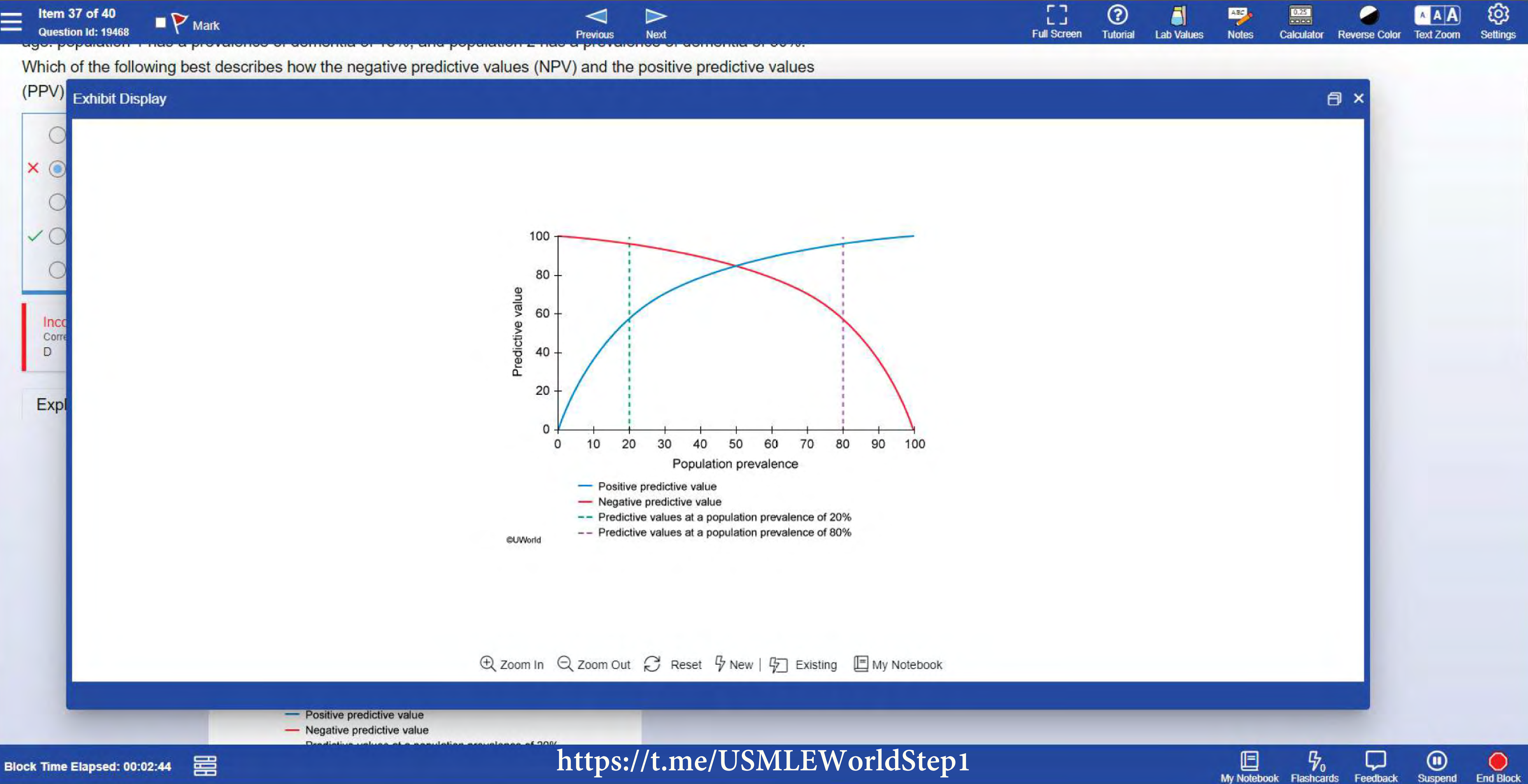
Explanation

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Which of the following best describes how the negative predictive values (NPV) and the positive predictive values (PPV)

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Predictive value
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Population prevalence
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— Positive predictive value
— Negative predictive value
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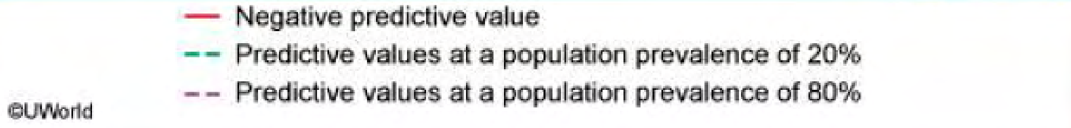

Predictive values are performance measures of diagnostic tests that are **dependent on the prevalence** of disease in a population of interest.

- **Negative predictive value** (NPV) is the probability (ie, likelihood) that an individual truly does not have the disease given a negative test result. NPV is equal to the number of individuals who do not have the disease and who test negative (true negatives [TN]) divided by all those with a negative test result (TN + false negatives [FN]): **NPV** = TN / (TN + FN).
- **Positive predictive value** (PPV) is the probability (ie, likelihood) that an individual truly does have the disease given a positive test result. PPV is equal to the number of individuals who have the disease and who test positive (true positives [TP]) divided by all those with a positive test result (TP + false positives [FP]): **PPV** = TP / (TP + FP).

Disease prevalence affects NPV by changing the number of TN and FN tests. It affects PPV by changing the number of TP and FP tests **(Choice A)**:

- Populations with exceptionally **low disease prevalence** (eg, prevalence close to 0%) have almost all TN (ie, more TN) with almost no TP (ie, fewer TP), and most positive tests would be FP (ie, more FP) with almost no FN (ie, fewer FN). In this scenario, NPV is close to 100%, and PPV is close to 0%. This explains why, with decreasing prevalence, **NPV increases** (more TN, fewer FN) and **PPV decreases** (fewer TP, more FP).
- Populations with exceptionally **high disease prevalence** (eg, prevalence close to 100%) have almost all TP (ie, more TP) with almost no TN (ie, fewer TN), and most negative tests would be FN (ie, more FN) with almost no FP (ie, fewer FP). In this scenario, NPV is close to 0%, and PPV is close to 100%. This explains why, with increasing prevalence, **NPV decreases** (fewer TN, more FN) and **PPV increases** (more TP, fewer FP).

(Choices B, C, and E) In this example, population 1 has a lower prevalence (15%) of dementia in women age ≥75 compared to population 2 (30%). Therefore, NPV in population 1 > NPV population 2, and PPV in population 1 <

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test positive (true positives [TP]) divided by all those with a positive test result (TP + false positives [FP]): **PPV** = TP / (TP + FP).

Disease prevalence affects NPV by changing the number of TN and FN tests. It affects PPV by changing the number of TP and FP tests **(Choice A)**:

- Populations with exceptionally **low disease prevalence** (eg, prevalence close to 0%) have almost all TN (ie, more TN) with almost no TP (ie, fewer TP), and most positive tests would be FP (ie, more FP) with almost no FN (ie, fewer FN). In this scenario, NPV is close to 100%, and PPV is close to 0%. This explains why, with decreasing prevalence, **NPV increases** (more TN, fewer FN) and **PPV decreases** (fewer TP, more FP).
- Populations with exceptionally **high disease prevalence** (eg, prevalence close to 100%) have almost all TP (ie, more TP) with almost no TN (ie, fewer TN), and most negative tests would be FN (ie, more FN) with almost no FP (ie, fewer FP). In this scenario, NPV is close to 0%, and PPV is close to 100%. This explains why, with increasing prevalence, **NPV decreases** (fewer TN, more FN) and **PPV increases** (more TP, fewer FP).

(Choices B, C, and E) In this example, population 1 has a lower prevalence (15%) of dementia in women age ≥75 compared to population 2 (30%). Therefore, NPV in population 1 > NPV population 2, and PPV in population 1 < PPV population 2.

Educational objective:
Predictive values change depending on the prevalence of disease in a study population. As disease prevalence increases, the positive predictive value increases, and the negative predictive value decreases.

References

- Diagnostic methods I: sensitivity, specificity, and other measures of accuracy.

Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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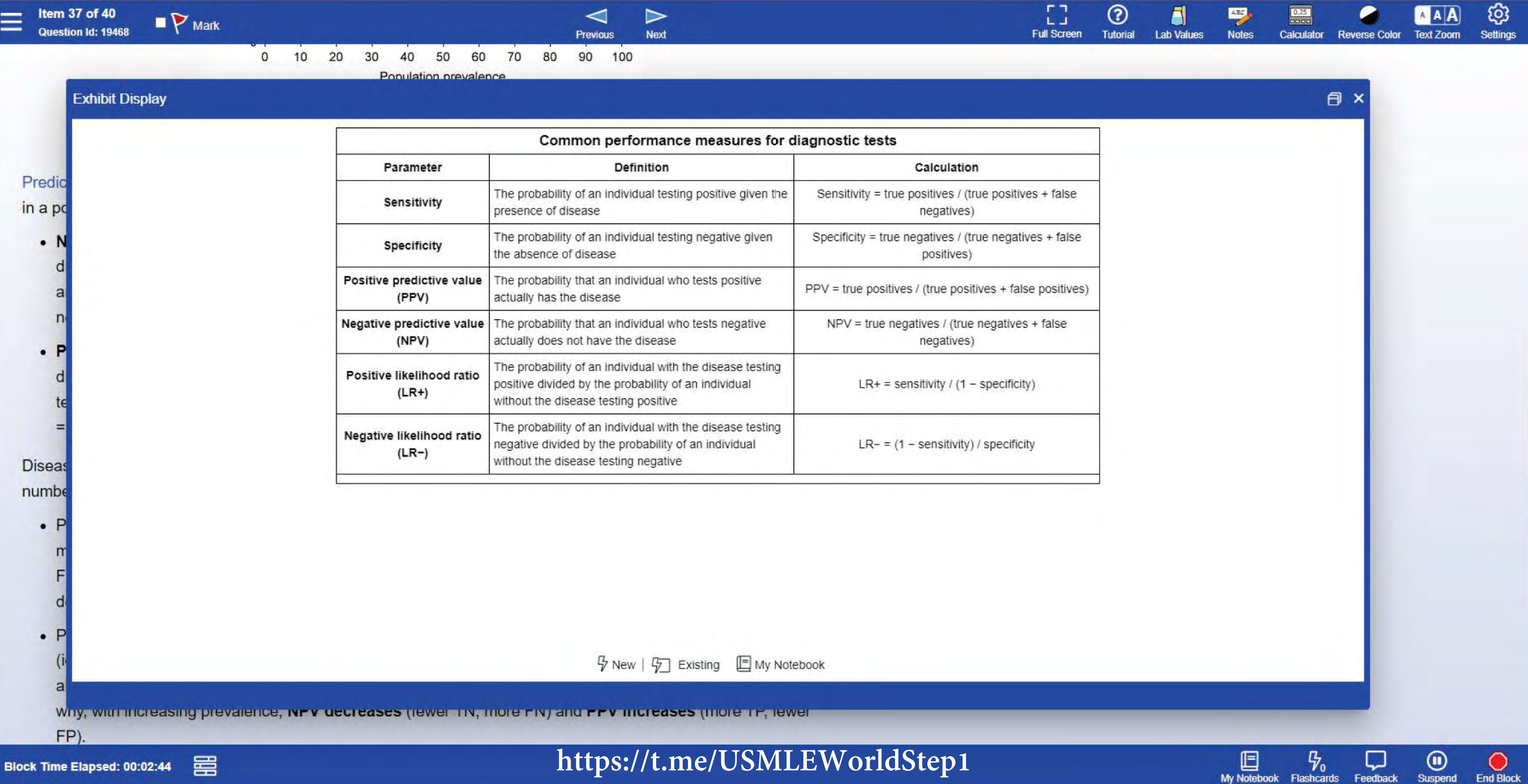
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Common performance measures for diagnostic tests

Parameter	Definition	Calculation
Sensitivity	The probability of an individual testing positive given the presence of disease	Sensitivity = true positives / (true positives + false negatives)
Specificity	The probability of an individual testing negative given the absence of disease	Specificity = true negatives / (true negatives + false positives)
Positive predictive value (PPV)	The probability that an individual who tests positive actually has the disease	PPV = true positives / (true positives + false positives)
Negative predictive value (NPV)	The probability that an individual who tests negative actually does not have the disease	NPV = true negatives / (true negatives + false negatives)
Positive likelihood ratio (LR+)	The probability of an individual with the disease testing positive divided by the probability of an individual without the disease testing positive	LR+ = sensitivity / (1 − specificity)
Negative likelihood ratio (LR−)	The probability of an individual with the disease testing negative divided by the probability of an individual without the disease testing negative	LR− = (1 − sensitivity) / specificity

why, with increasing prevalence, **NPV decreases** (fewer TN, more FN) and **PPV increases** (more TP, fewer FP).

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A research group is studying the correlation between BMI and blood pressure in a random sample of children age 12-16. After collecting data, they conduct a correlation analysis at a 1% significance level. The researchers find that BMI correlates with systolic blood pressure with a coefficient of $r = 0.46$ ($p < 0.001$) and diastolic blood pressure with a coefficient of $r = 0.37$ ($p < 0.001$). Which of the following is the most accurate interpretation of these results?

○ A. An increase in BMI causes a statistically significant increase in blood pressure in children

○ B. Childhood obesity significantly increases the risk of cardiovascular disease later in life

○ C. There is a statistically significant negative linear relationship between BMI and blood pressure in children

○ D. There is a statistically significant positive linear relationship between BMI and blood pressure in children

○ E. There is no statistically significant linear relationship between BMI and blood pressure in children

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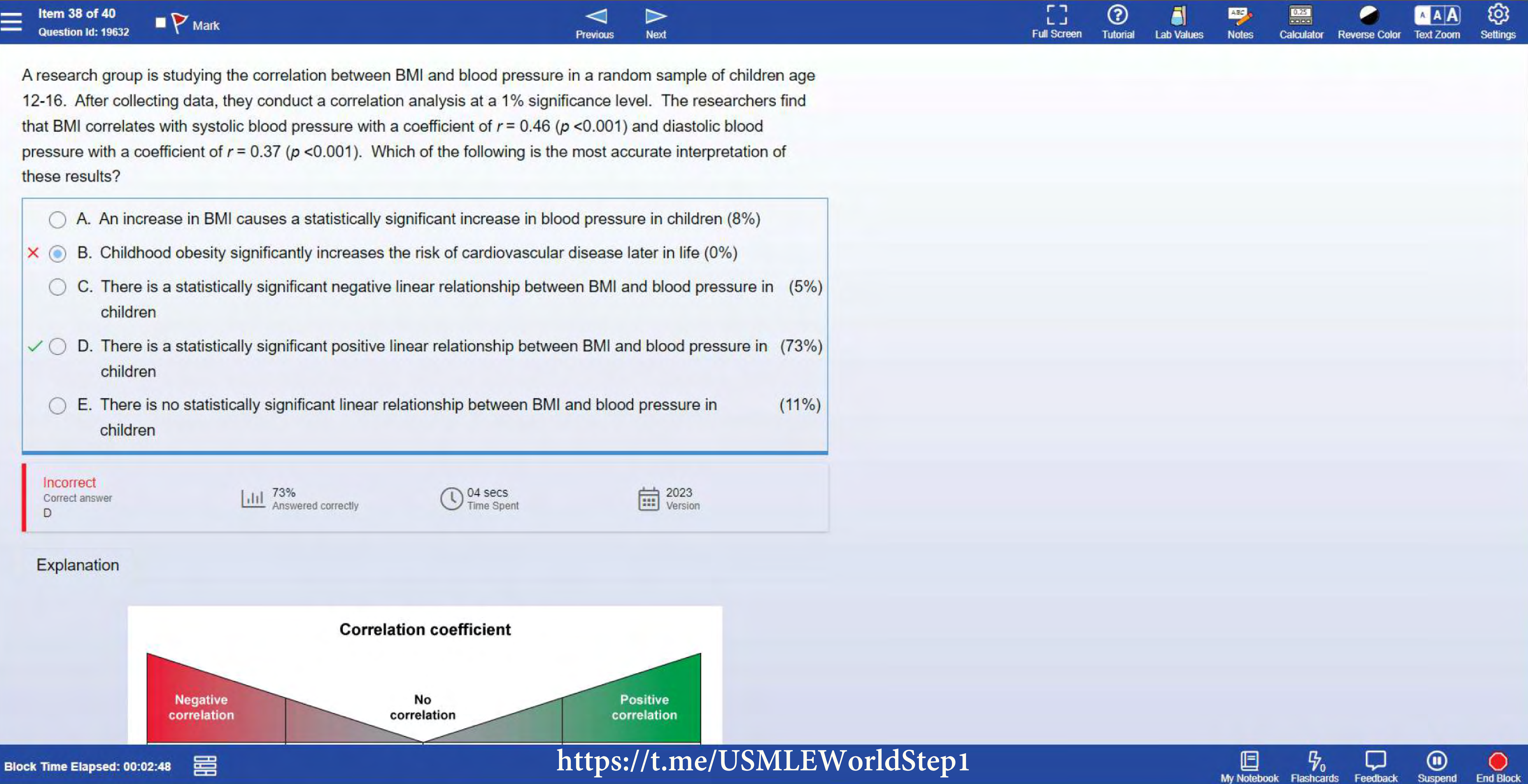
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A research group is studying the correlation between BMI and blood pressure in a random sample of children age 12-16. After collecting data, they conduct a correlation analysis at a 1% significance level. The researchers find that BMI correlates with systolic blood pressure with a coefficient of $r = 0.46$ ($p < 0.001$) and diastolic blood pressure with a coefficient of $r = 0.37$ ($p < 0.001$). Which of the following is the most accurate interpretation of these results?

○ A. An increase in BMI causes a statistically significant increase in blood pressure in children (8%)

✗ ● B. Childhood obesity significantly increases the risk of cardiovascular disease later in life (0%)

○ C. There is a statistically significant negative linear relationship between BMI and blood pressure in children (5%)

✓ ○ D. There is a statistically significant positive linear relationship between BMI and blood pressure in children (73%)

○ E. There is no statistically significant linear relationship between BMI and blood pressure in children (11%)

Incorrect
Correct answer
D

73%
Answered correctly

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Explanation

Correlation coefficient

Negative correlation
No correlation
Positive correlation
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Explanation

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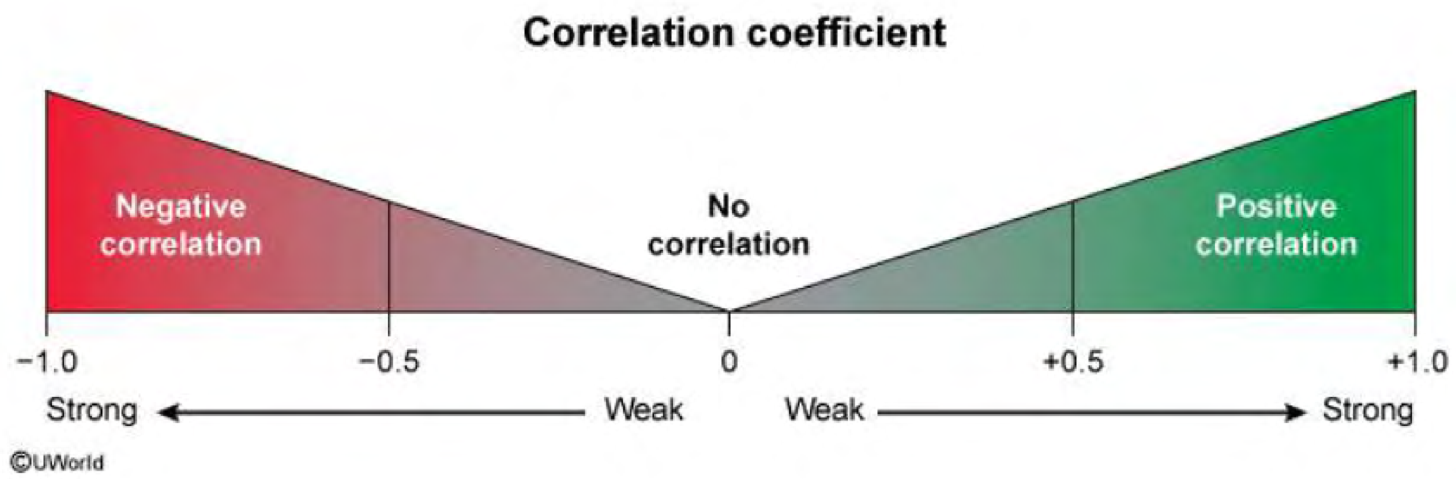
Correlation coefficient
Negative correlation
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Positive correlation
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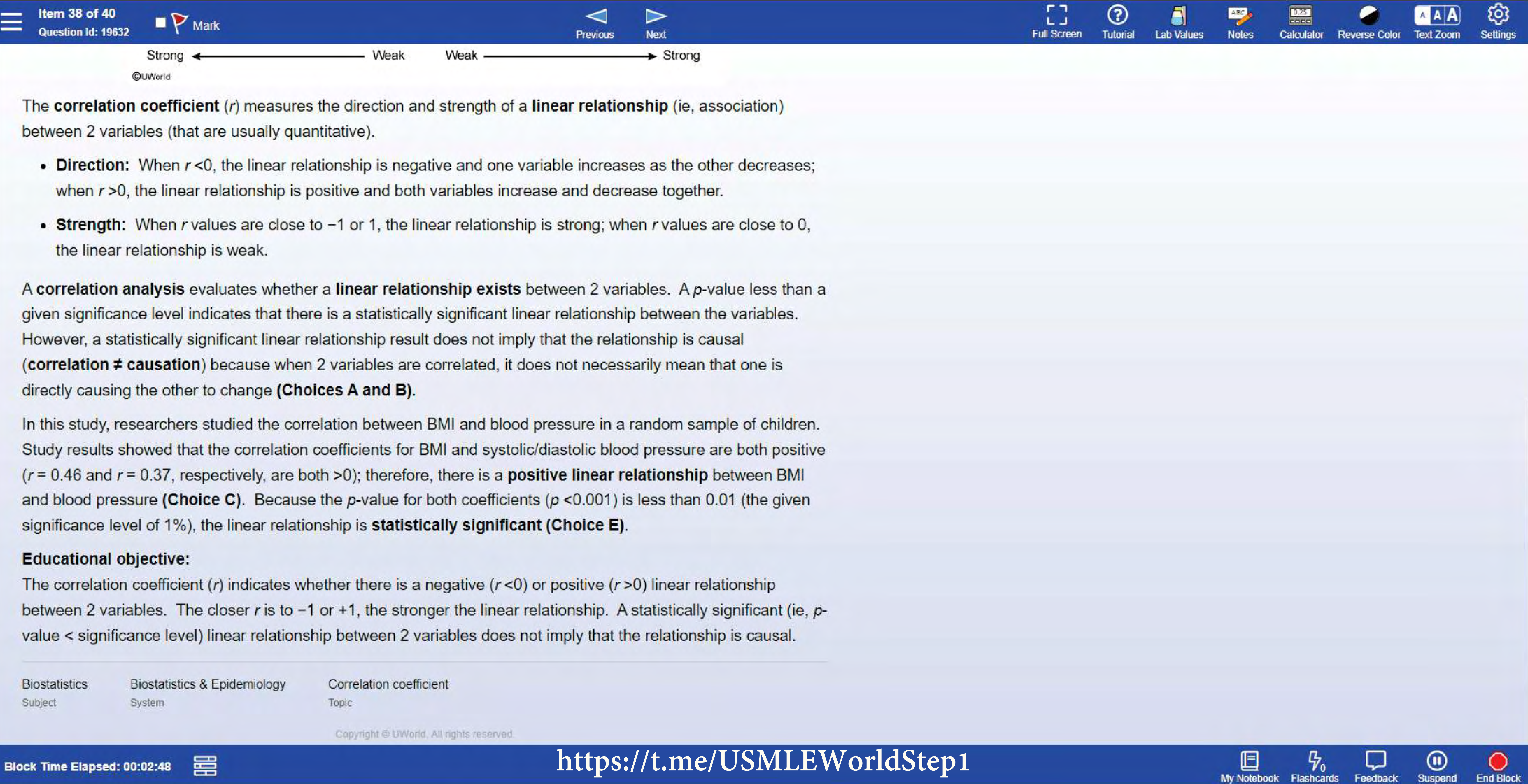
and blood pressure **(Choice C)**. Because the *p*-value for both coefficients (p <0.001) is less than 0.01 (the given significance level of 1%), the linear relationship is **statistically significant (Choice E)**.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Strong
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The **correlation coefficient** (*r*) measures the direction and strength of a **linear relationship** (ie, association) between 2 variables (that are usually quantitative).

- **Direction:** When $r < 0$, the linear relationship is negative and one variable increases as the other decreases; when $r > 0$, the linear relationship is positive and both variables increase and decrease together.
- **Strength:** When *r* values are close to −1 or 1, the linear relationship is strong; when *r* values are close to 0, the linear relationship is weak.

A **correlation analysis** evaluates whether a **linear relationship exists** between 2 variables. A *p*-value less than a given significance level indicates that there is a statistically significant linear relationship between the variables. However, a statistically significant linear relationship result does not imply that the relationship is causal (**correlation ≠ causation**) because when 2 variables are correlated, it does not necessarily mean that one is directly causing the other to change **(Choices A and B)**.

In this study, researchers studied the correlation between BMI and blood pressure in a random sample of children. Study results showed that the correlation coefficients for BMI and systolic/diastolic blood pressure are both positive ($r = 0.46$ and $r = 0.37$, respectively, are both >0); therefore, there is a **positive linear relationship** between BMI and blood pressure **(Choice C)**. Because the *p*-value for both coefficients ($p < 0.001$) is less than 0.01 (the given significance level of 1%), the linear relationship is **statistically significant (Choice E)**.

Educational objective:

The correlation coefficient (*r*) indicates whether there is a negative ($r < 0$) or positive ($r > 0$) linear relationship between 2 variables. The closer *r* is to −1 or +1, the stronger the linear relationship. A statistically significant (ie, *p*-value < significance level) linear relationship between 2 variables does not imply that the relationship is causal.

Biostatistics	Biostatistics & Epidemiology	Correlation coefficient
Subject	System	Topic

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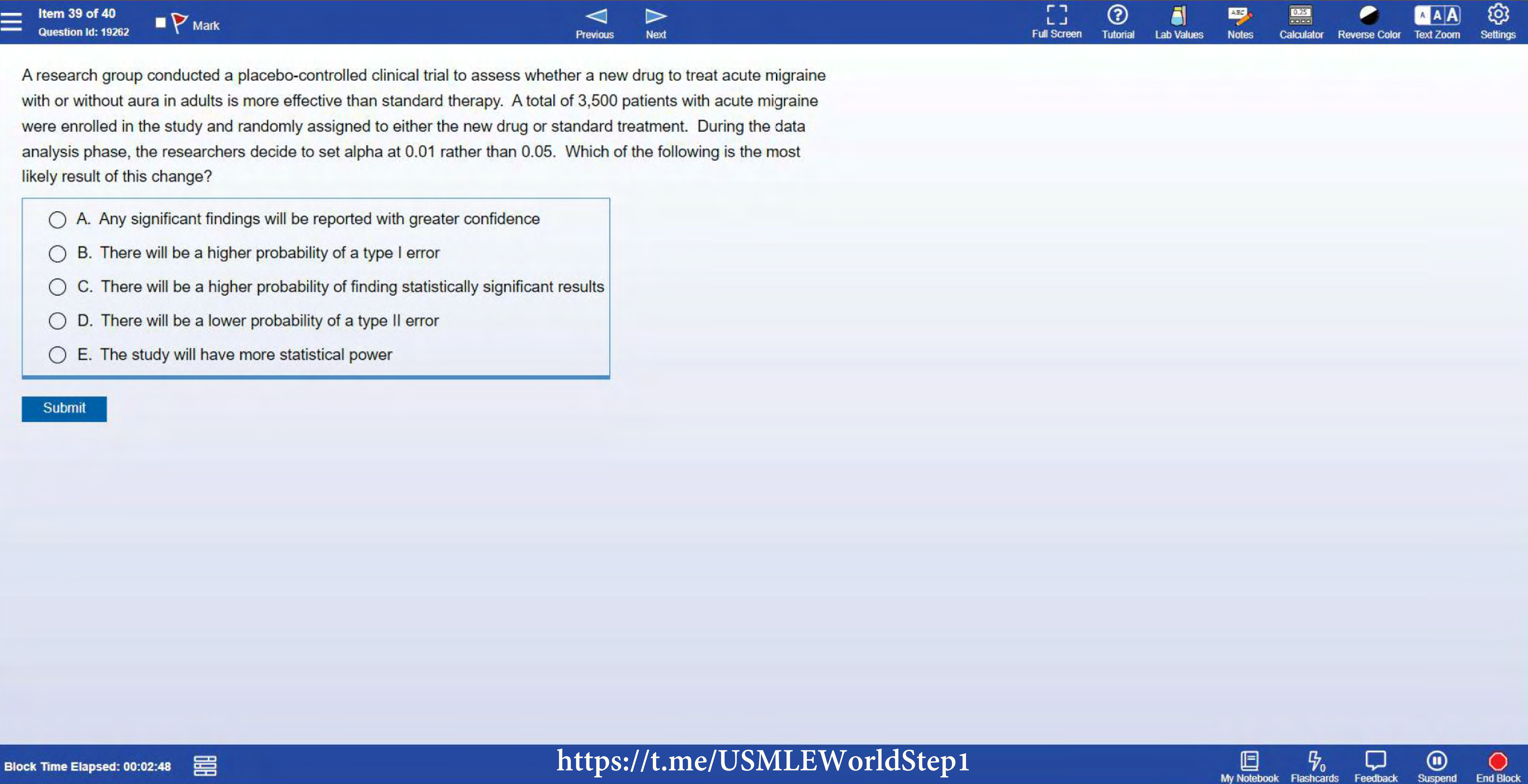
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A research group conducted a placebo-controlled clinical trial to assess whether a new drug to treat acute migraine with or without aura in adults is more effective than standard therapy. A total of 3,500 patients with acute migraine were enrolled in the study and randomly assigned to either the new drug or standard treatment. During the data analysis phase, the researchers decide to set alpha at 0.01 rather than 0.05. Which of the following is the most likely result of this change?

○ A. Any significant findings will be reported with greater confidence
○ B. There will be a higher probability of a type I error
○ C. There will be a higher probability of finding statistically significant results
○ D. There will be a lower probability of a type II error
○ E. The study will have more statistical power

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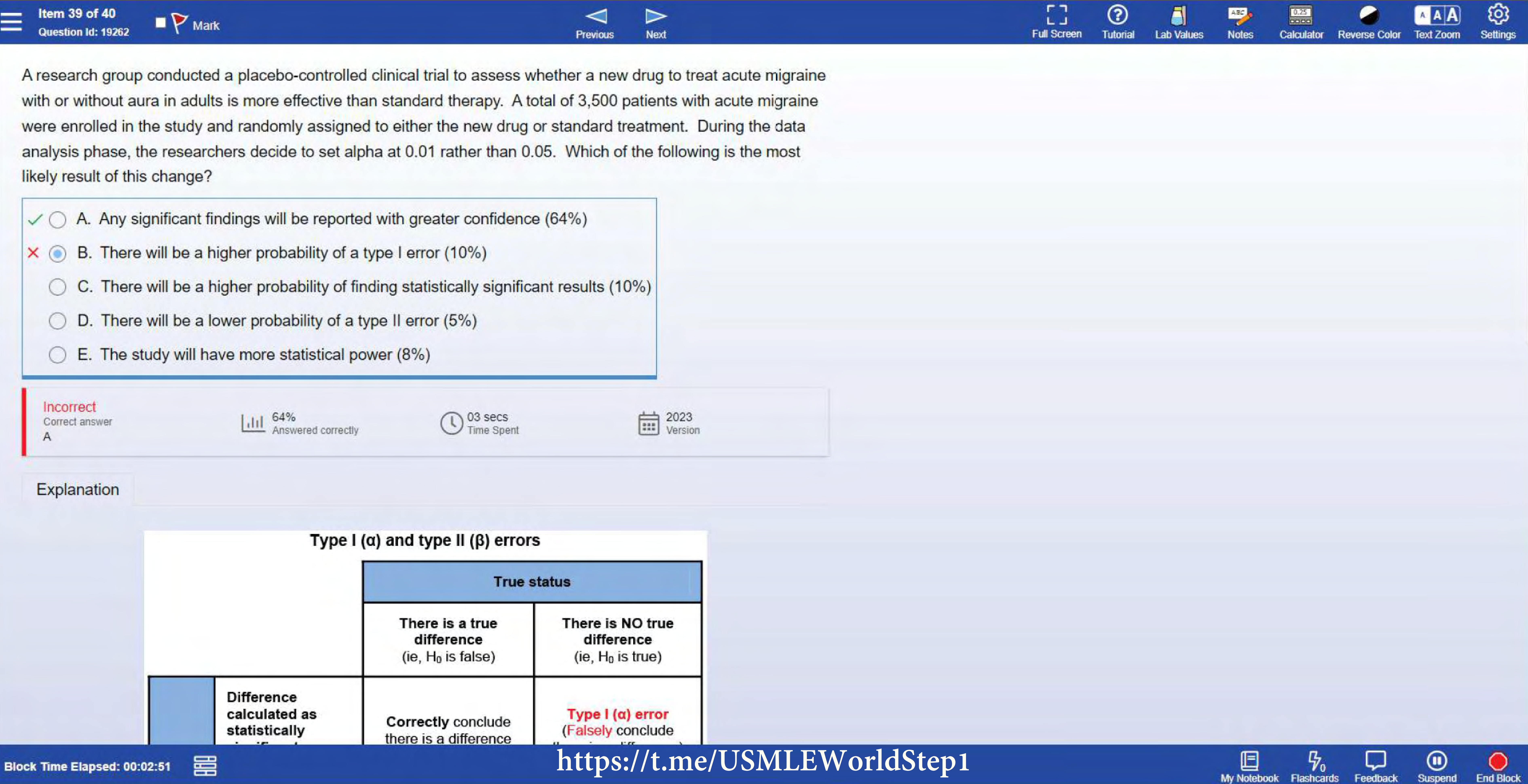
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A research group conducted a placebo-controlled clinical trial to assess whether a new drug to treat acute migraine with or without aura in adults is more effective than standard therapy. A total of 3,500 patients with acute migraine were enrolled in the study and randomly assigned to either the new drug or standard treatment. During the data analysis phase, the researchers decide to set alpha at 0.01 rather than 0.05. Which of the following is the most likely result of this change?

- ✓ ○ A. Any significant findings will be reported with greater confidence (64%)
- ✗ ● B. There will be a higher probability of a type I error (10%)
- ○ C. There will be a higher probability of finding statistically significant results (10%)
- ○ D. There will be a lower probability of a type II error (5%)
- ○ E. The study will have more statistical power (8%)

Incorrect
Correct answer
A

64%
Answered correctly

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Explanation

Type I (α) and type II (β) errors

		True status	
		There is a true difference (ie, H_0 is false)	**There is NO true difference** (ie, H_0 is true)
	Difference calculated as statistically	**Correctly** conclude there is a difference	**Type I (α) error** (Falsely conclude

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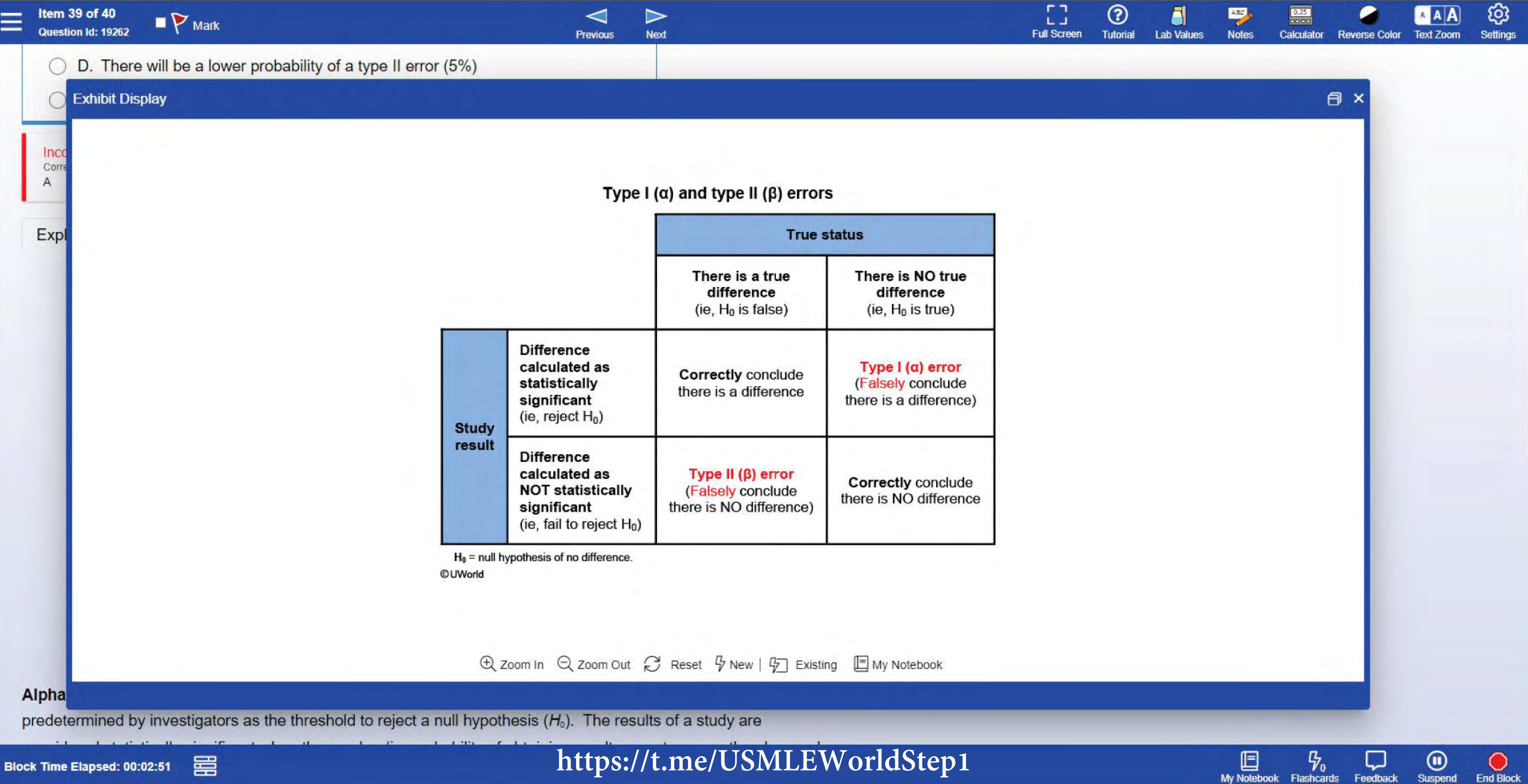
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○ D. There will be a lower probability of a type II error (5%)

○

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Type I (α) and type II (β) errors

		True status	
		There is a true difference (ie, H_0 is false)	**There is NO true difference** (ie, H_0 is true)
Study result	**Difference calculated as statistically significant** (ie, reject H_0)	**Correctly** conclude there is a difference	**Type I (α) error** (Falsely conclude there is a difference)
	Difference calculated as NOT statistically significant (ie, fail to reject H_0)	**Type II (β) error** (Falsely conclude there is NO difference)	**Correctly** conclude there is NO difference

H_0 = null hypothesis of no difference.

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Alpha

predetermined by investigators as the threshold to reject a null hypothesis (H_0). The results of a study are

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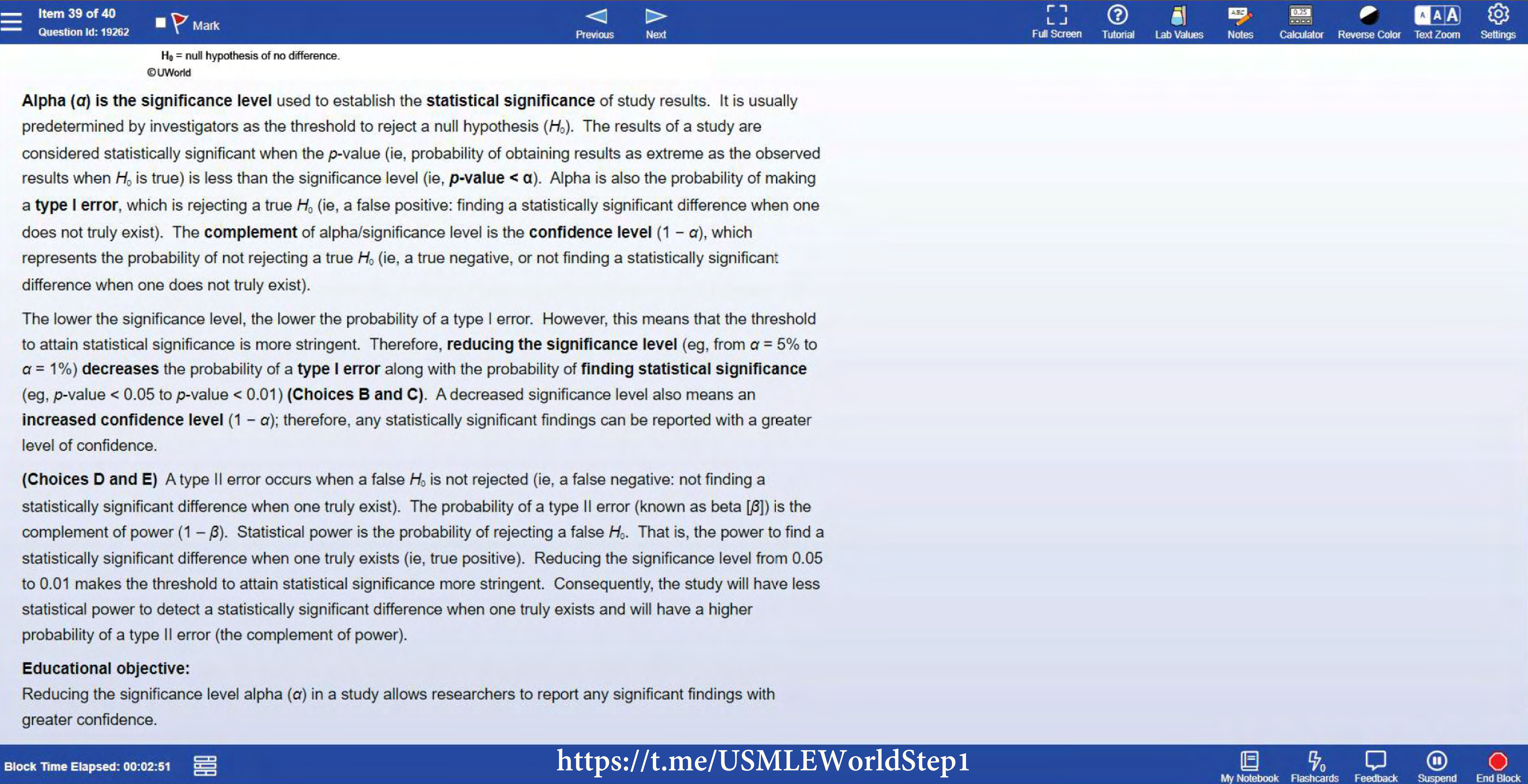

H_0 = null hypothesis of no difference.

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Alpha (α) is the significance level used to establish the **statistical significance** of study results. It is usually predetermined by investigators as the threshold to reject a null hypothesis (H_0). The results of a study are considered statistically significant when the *p*-value (ie, probability of obtaining results as extreme as the observed results when H_0 is true) is less than the significance level (ie, **p-value < α**). Alpha is also the probability of making a **type I error**, which is rejecting a true H_0 (ie, a false positive: finding a statistically significant difference when one does not truly exist). The **complement** of alpha/significance level is the **confidence level** ($1 - \alpha$), which represents the probability of not rejecting a true H_0 (ie, a true negative, or not finding a statistically significant difference when one does not truly exist).

The lower the significance level, the lower the probability of a type I error. However, this means that the threshold to attain statistical significance is more stringent. Therefore, **reducing the significance level** (eg, from α = 5% to α = 1%) **decreases** the probability of a **type I error** along with the probability of **finding statistical significance** (eg, *p*-value < 0.05 to *p*-value < 0.01) **(Choices B and C)**. A decreased significance level also means an **increased confidence level** ($1 - \alpha$); therefore, any statistically significant findings can be reported with a greater level of confidence.

(Choices D and E) A type II error occurs when a false H_0 is not rejected (ie, a false negative: not finding a statistically significant difference when one truly exist). The probability of a type II error (known as beta [β]) is the complement of power ($1 - \beta$). Statistical power is the probability of rejecting a false H_0. That is, the power to find a statistically significant difference when one truly exists (ie, true positive). Reducing the significance level from 0.05 to 0.01 makes the threshold to attain statistical significance more stringent. Consequently, the study will have less statistical power to detect a statistically significant difference when one truly exists and will have a higher probability of a type II error (the complement of power).

Educational objective:

Reducing the significance level alpha (α) in a study allows researchers to report any significant findings with greater confidence.

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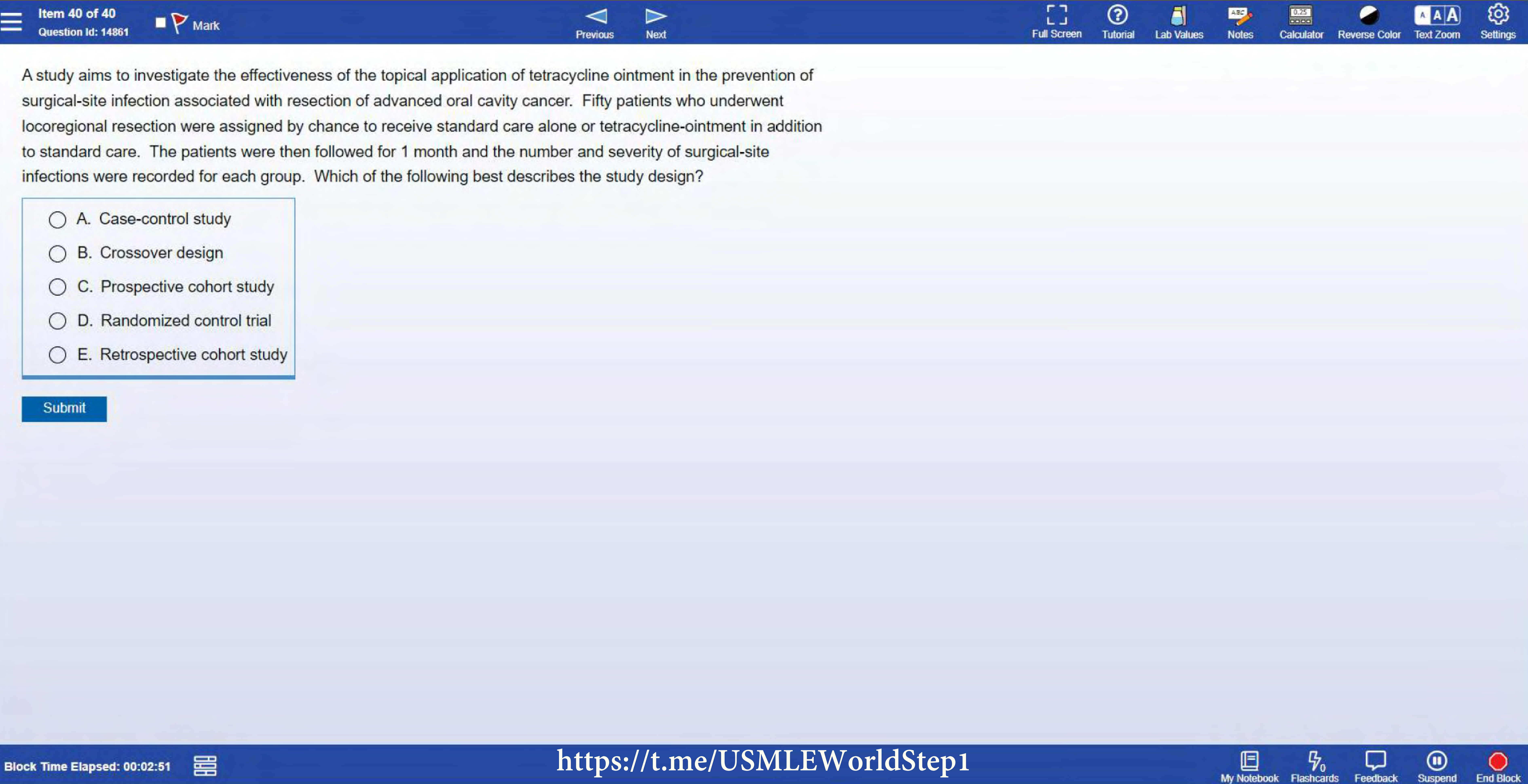
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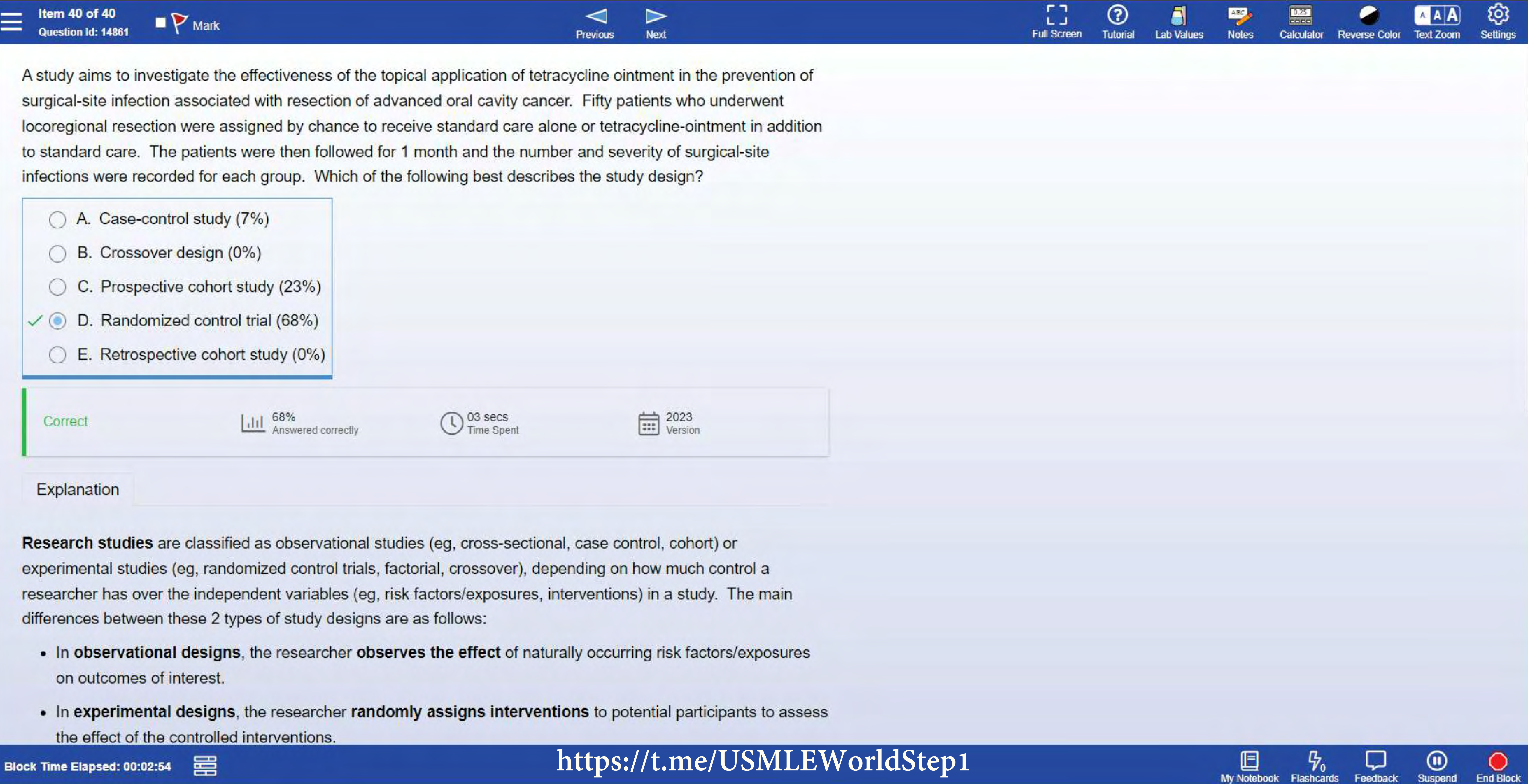
A study aims to investigate the effectiveness of the topical application of tetracycline ointment in the prevention of surgical-site infection associated with resection of advanced oral cavity cancer. Fifty patients who underwent locoregional resection were assigned by chance to receive standard care alone or tetracycline-ointment in addition to standard care. The patients were then followed for 1 month and the number and severity of surgical-site infections were recorded for each group. Which of the following best describes the study design?

○ A. Case-control study
○ B. Crossover design
○ C. Prospective cohort study
○ D. Randomized control trial
○ E. Retrospective cohort study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○ A. Case-control study (7%)
○ B. Crossover design (0%)
○ C. Prospective cohort study (23%)
✓ ● D. Randomized control trial (68%)
○ E. Retrospective cohort study (0%)

Correct

68% Answered correctly

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Explanation

Research studies are classified as observational studies (eg, cross-sectional, case control, cohort) or experimental studies (eg, randomized control trials, factorial, crossover), depending on how much control a researcher has over the independent variables (eg, risk factors/exposures, interventions) in a study. The main differences between these 2 types of study designs are as follows:

- In **observational designs**, the researcher **observes the effect** of naturally occurring risk factors/exposures on outcomes of interest.
- In **experimental designs**, the researcher **randomly assigns interventions** to potential participants to assess the effect of the controlled interventions.

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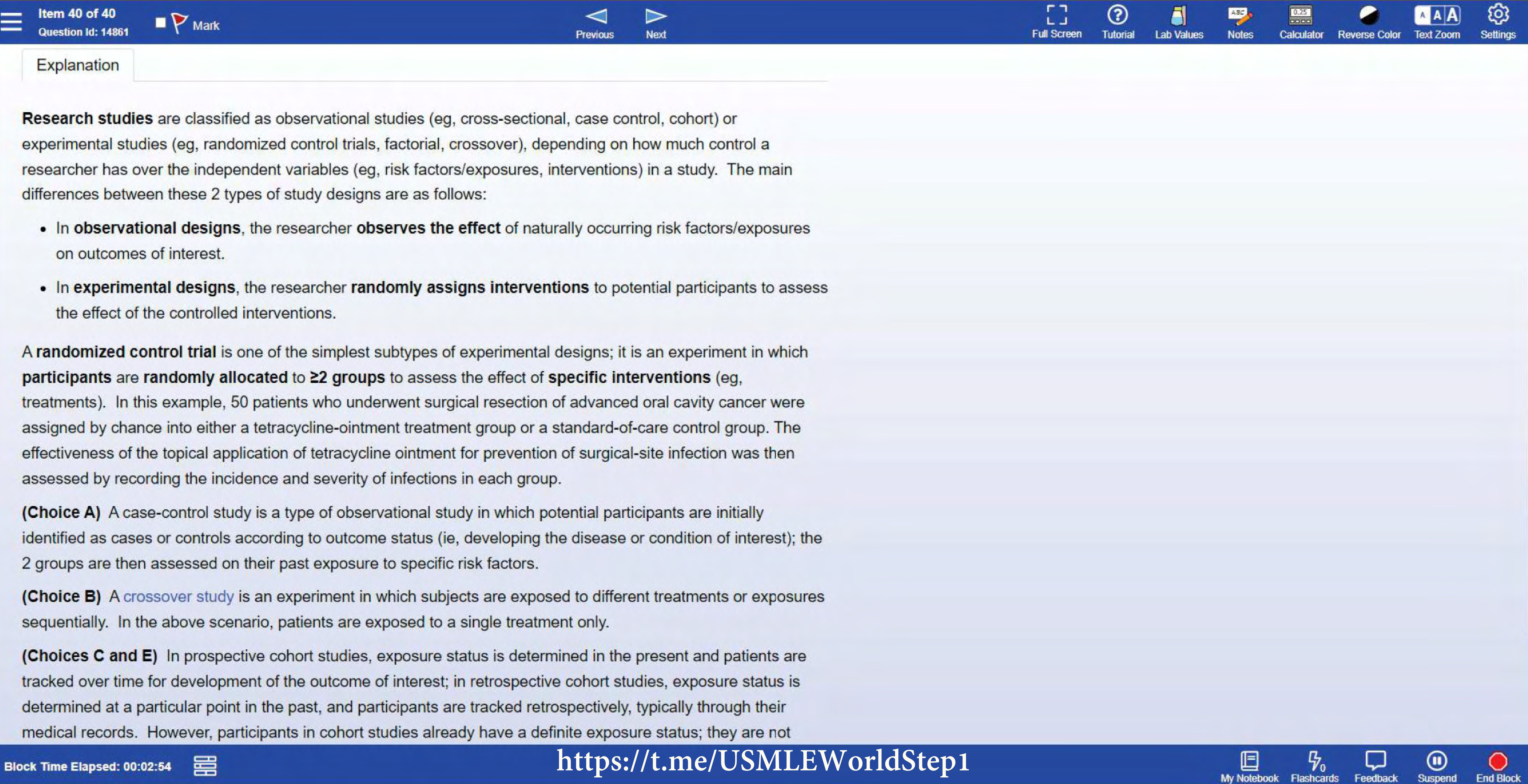


Research studies are classified as observational studies (eg, cross-sectional, case control, cohort) or experimental studies (eg, randomized control trials, factorial, crossover), depending on how much control a researcher has over the independent variables (eg, risk factors/exposures, interventions) in a study. The main differences between these 2 types of study designs are as follows:

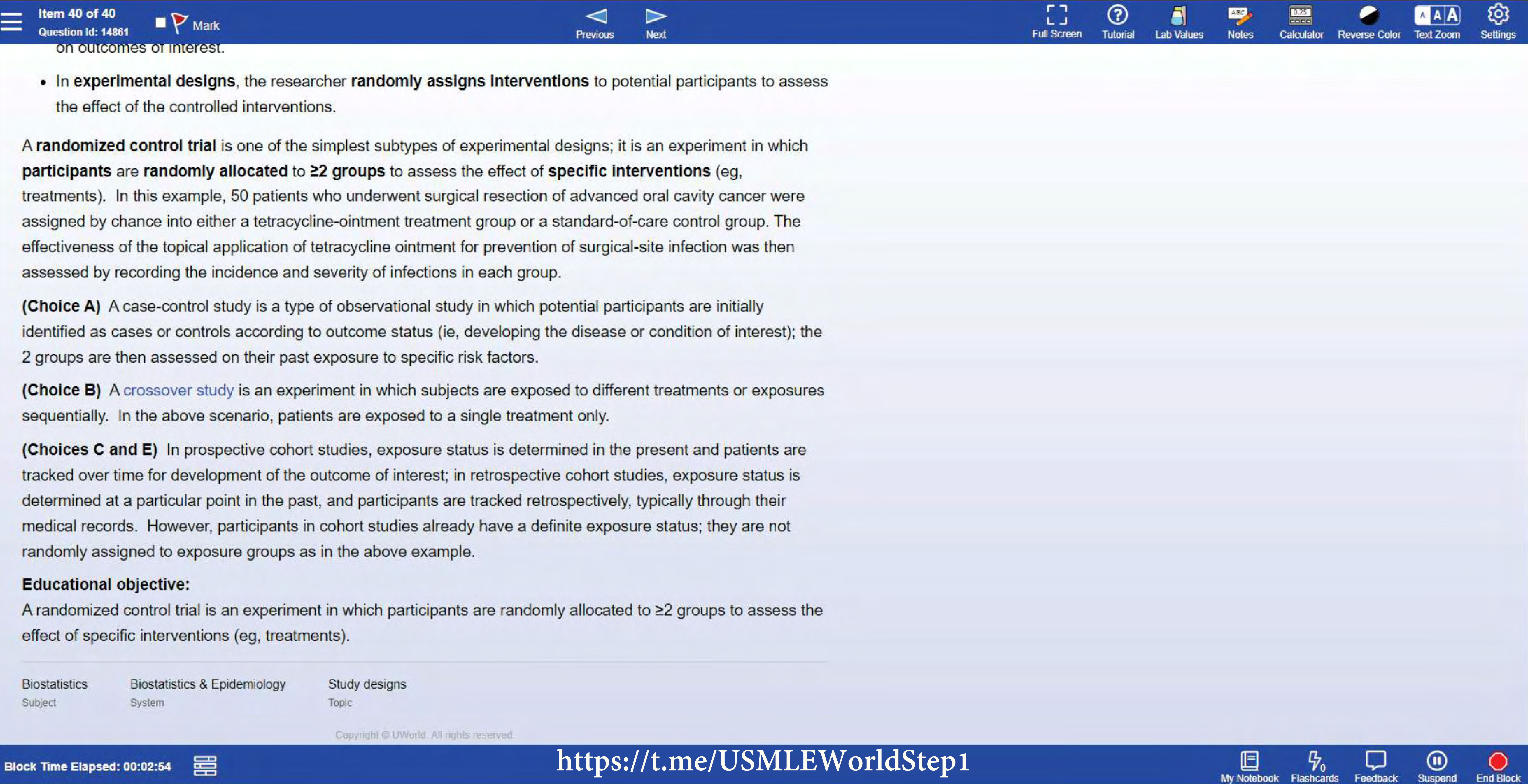
- In **observational designs**, the researcher **observes the effect** of naturally occurring risk factors/exposures on outcomes of interest.
- In **experimental designs**, the researcher **randomly assigns interventions** to potential participants to assess the effect of the controlled interventions.

A **randomized control trial** is one of the simplest subtypes of experimental designs; it is an experiment in which **participants** are **randomly allocated** to **≥2 groups** to assess the effect of **specific interventions** (eg, treatments). In this example, 50 patients who underwent surgical resection of advanced oral cavity cancer were assigned by chance into either a tetracycline-ointment treatment group or a standard-of-care control group. The effectiveness of the topical application of tetracycline ointment for prevention of surgical-site infection was then assessed by recording the incidence and severity of infections in each group.

(Choice A) A case-control study is a type of observational study in which potential participants are initially identified as cases or controls according to outcome status (ie, developing the disease or condition of interest); the 2 groups are then assessed on their past exposure to specific risk factors.

(Choice B) A crossover study is an experiment in which subjects are exposed to different treatments or exposures sequentially. In the above scenario, patients are exposed to a single treatment only.

(Choices C and E) In prospective cohort studies, exposure status is determined in the present and patients are tracked over time for development of the outcome of interest; in retrospective cohort studies, exposure status is determined at a particular point in the past, and participants are tracked retrospectively, typically through their medical records. However, participants in cohort studies already have a definite exposure status; they are not



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Educational objective:

A randomized control trial is an experiment in which participants are randomly allocated to ≥2 groups to assess the effect of specific interventions (eg, treatments).

Biostatistics	Biostatistics & Epidemiology	Study designs
Subject	System	Topic

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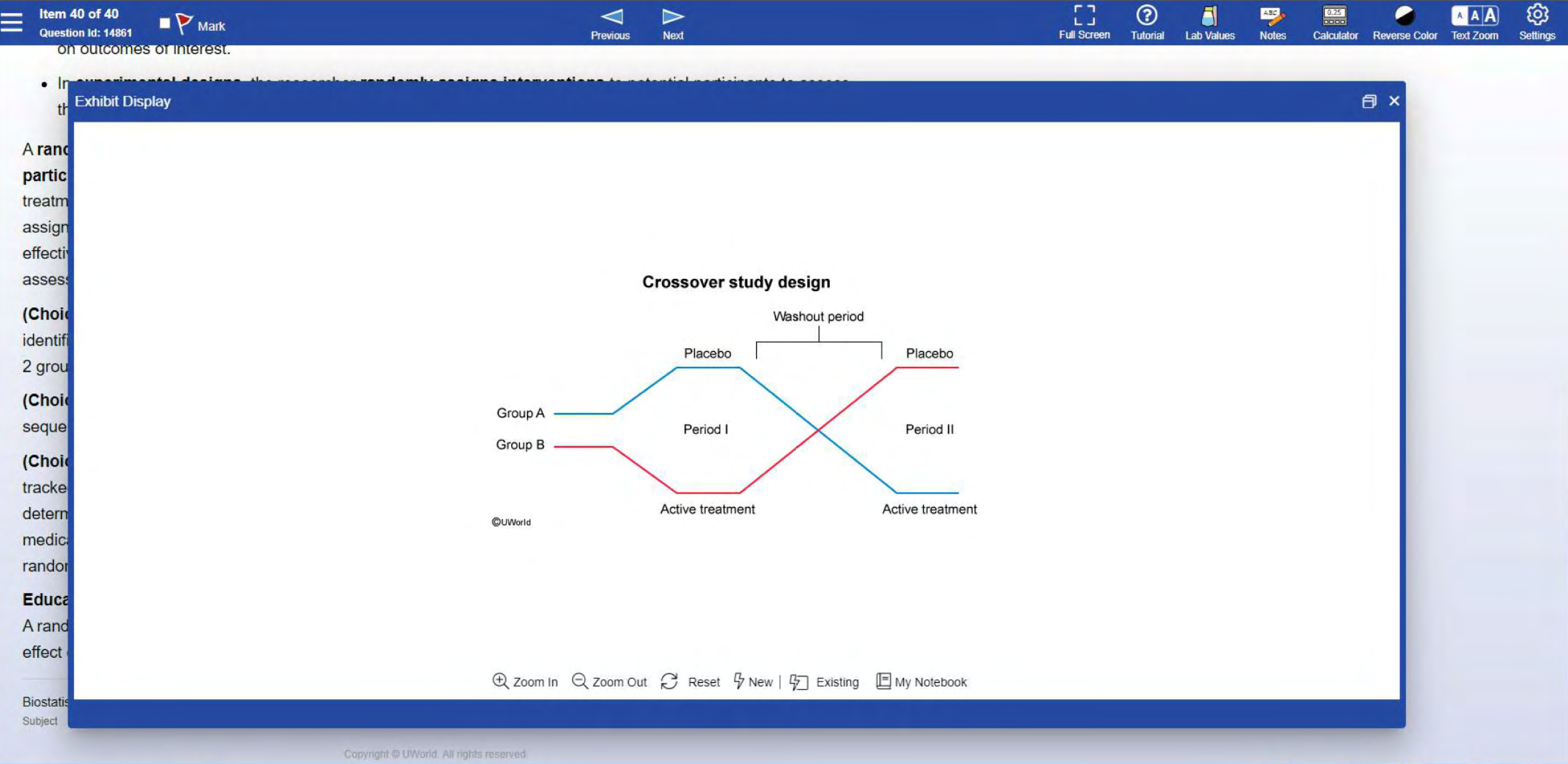
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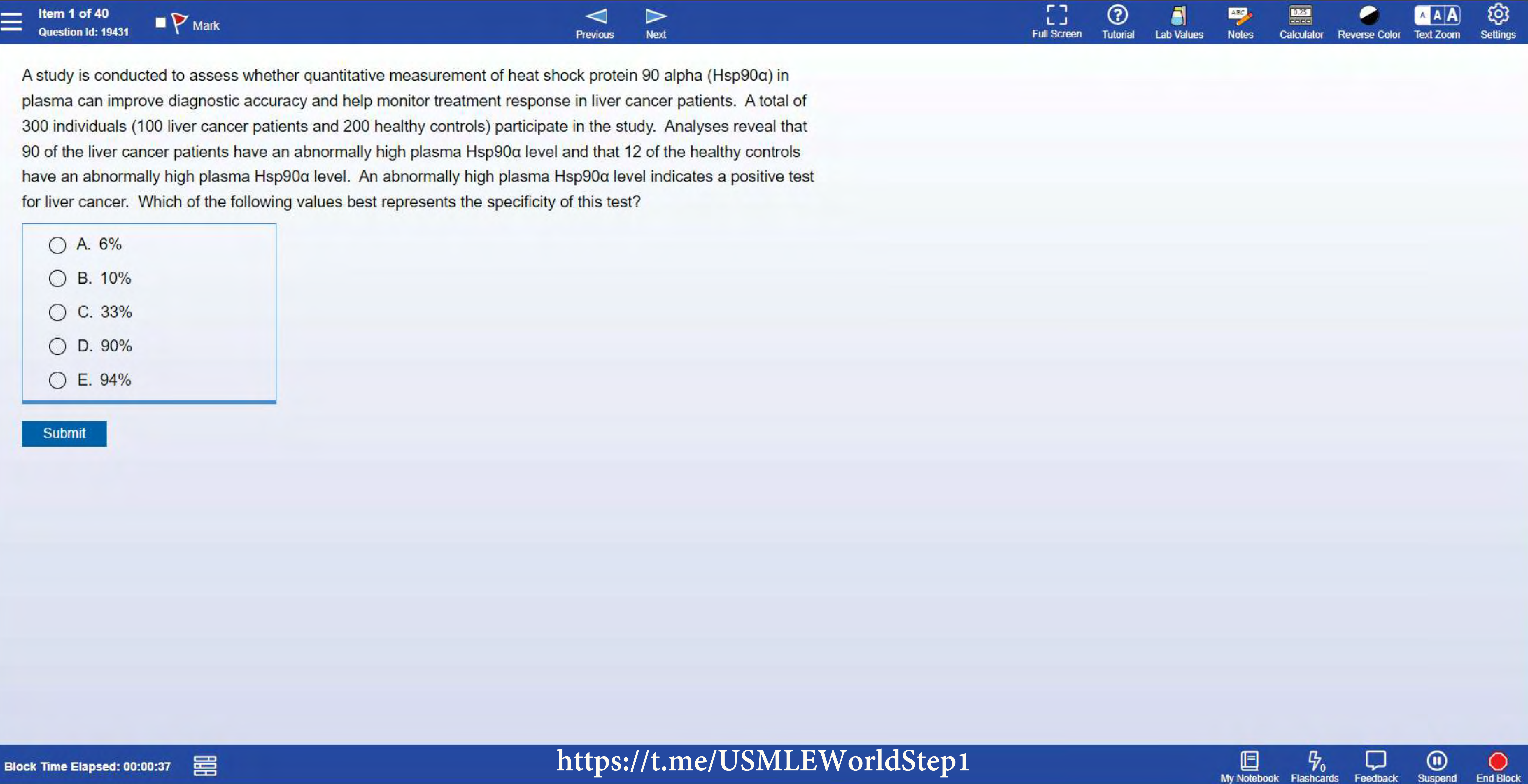
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A study is conducted to assess whether quantitative measurement of heat shock protein 90 alpha (Hsp90α) in plasma can improve diagnostic accuracy and help monitor treatment response in liver cancer patients. A total of 300 individuals (100 liver cancer patients and 200 healthy controls) participate in the study. Analyses reveal that 90 of the liver cancer patients have an abnormally high plasma Hsp90α level and that 12 of the healthy controls have an abnormally high plasma Hsp90α level. An abnormally high plasma Hsp90α level indicates a positive test for liver cancer. Which of the following values best represents the specificity of this test?

○ A. 6%
○ B. 10%
○ C. 33%
○ D. 90%
○ E. 94%

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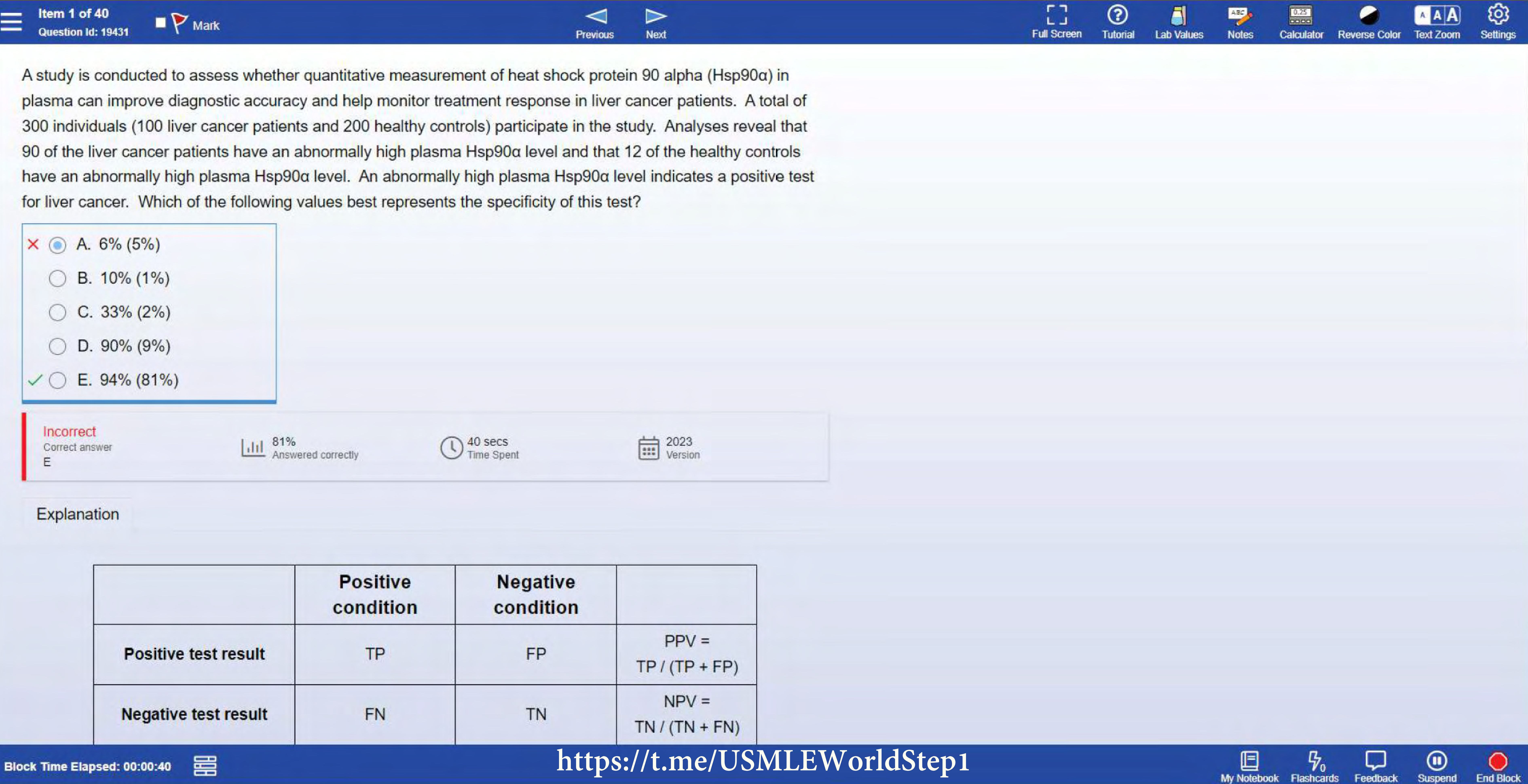
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✗ ● A. 6% (5%)
○ B. 10% (1%)
○ C. 33% (2%)
○ D. 90% (9%)
✓ ○ E. 94% (81%)

Incorrect
Correct answer
E

81%
Answered correctly

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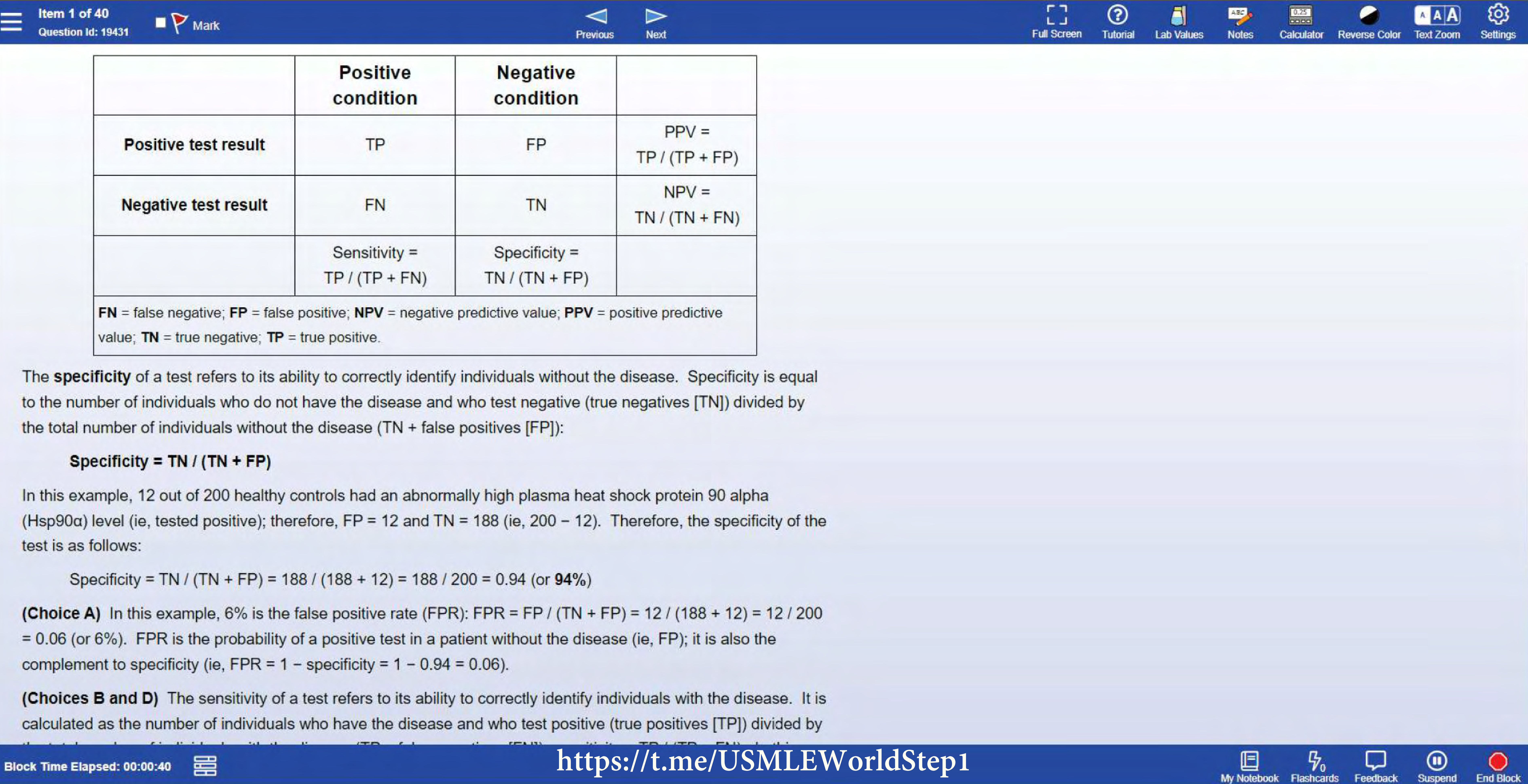
Explanation

	Positive condition	**Negative condition**	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)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	Positive condition	**Negative condition**	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

The **specificity** of a test refers to its ability to correctly identify individuals without the disease. Specificity is equal to the number of individuals who do not have the disease and who test negative (true negatives [TN]) divided by the total number of individuals without the disease (TN + false positives [FP]):

Specificity = TN / (TN + FP)

In this example, 12 out of 200 healthy controls had an abnormally high plasma heat shock protein 90 alpha (Hsp90α) level (ie, tested positive); therefore, FP = 12 and TN = 188 (ie, 200 − 12). Therefore, the specificity of the test is as follows:

Specificity = TN / (TN + FP) = 188 / (188 + 12) = 188 / 200 = 0.94 (or **94%**)

(Choice A) In this example, 6% is the false positive rate (FPR): FPR = FP / (TN + FP) = 12 / (188 + 12) = 12 / 200 = 0.06 (or 6%). FPR is the probability of a positive test in a patient without the disease (ie, FP); it is also the complement to specificity (ie, FPR = 1 − specificity = 1 − 0.94 = 0.06).

(Choices B and D) The sensitivity of a test refers to its ability to correctly identify individuals with the disease. It is calculated as the number of individuals who have the disease and who test positive (true positives [TP]) divided by

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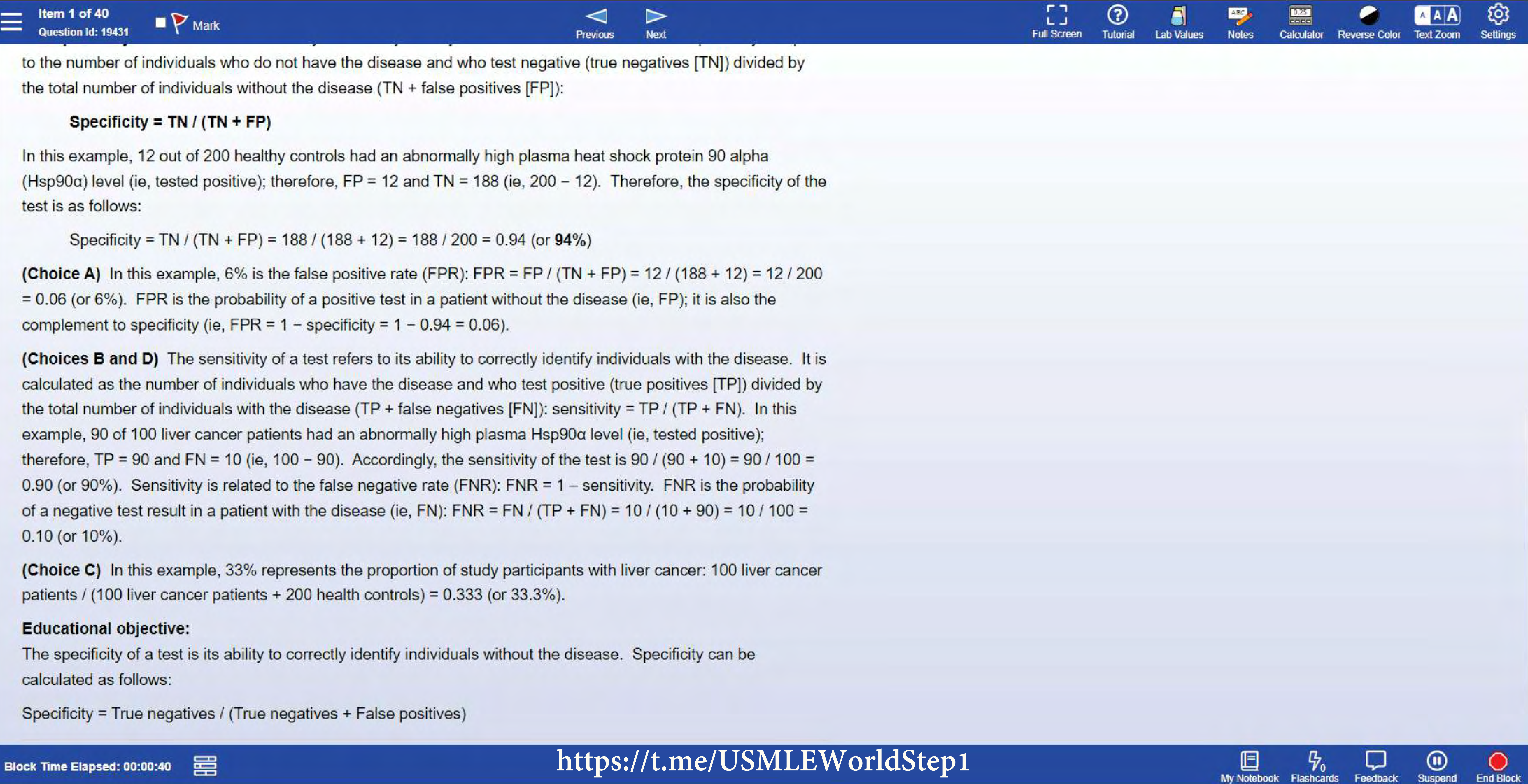
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to the number of individuals who do not have the disease and who test negative (true negatives [TN]) divided by the total number of individuals without the disease (TN + false positives [FP]):

Specificity = TN / (TN + FP)

In this example, 12 out of 200 healthy controls had an abnormally high plasma heat shock protein 90 alpha (Hsp90α) level (ie, tested positive); therefore, FP = 12 and TN = 188 (ie, 200 − 12). Therefore, the specificity of the test is as follows:

Specificity = TN / (TN + FP) = 188 / (188 + 12) = 188 / 200 = 0.94 (or **94%**)

(Choice A) In this example, 6% is the false positive rate (FPR): FPR = FP / (TN + FP) = 12 / (188 + 12) = 12 / 200 = 0.06 (or 6%). FPR is the probability of a positive test in a patient without the disease (ie, FP); it is also the complement to specificity (ie, FPR = 1 − specificity = 1 − 0.94 = 0.06).

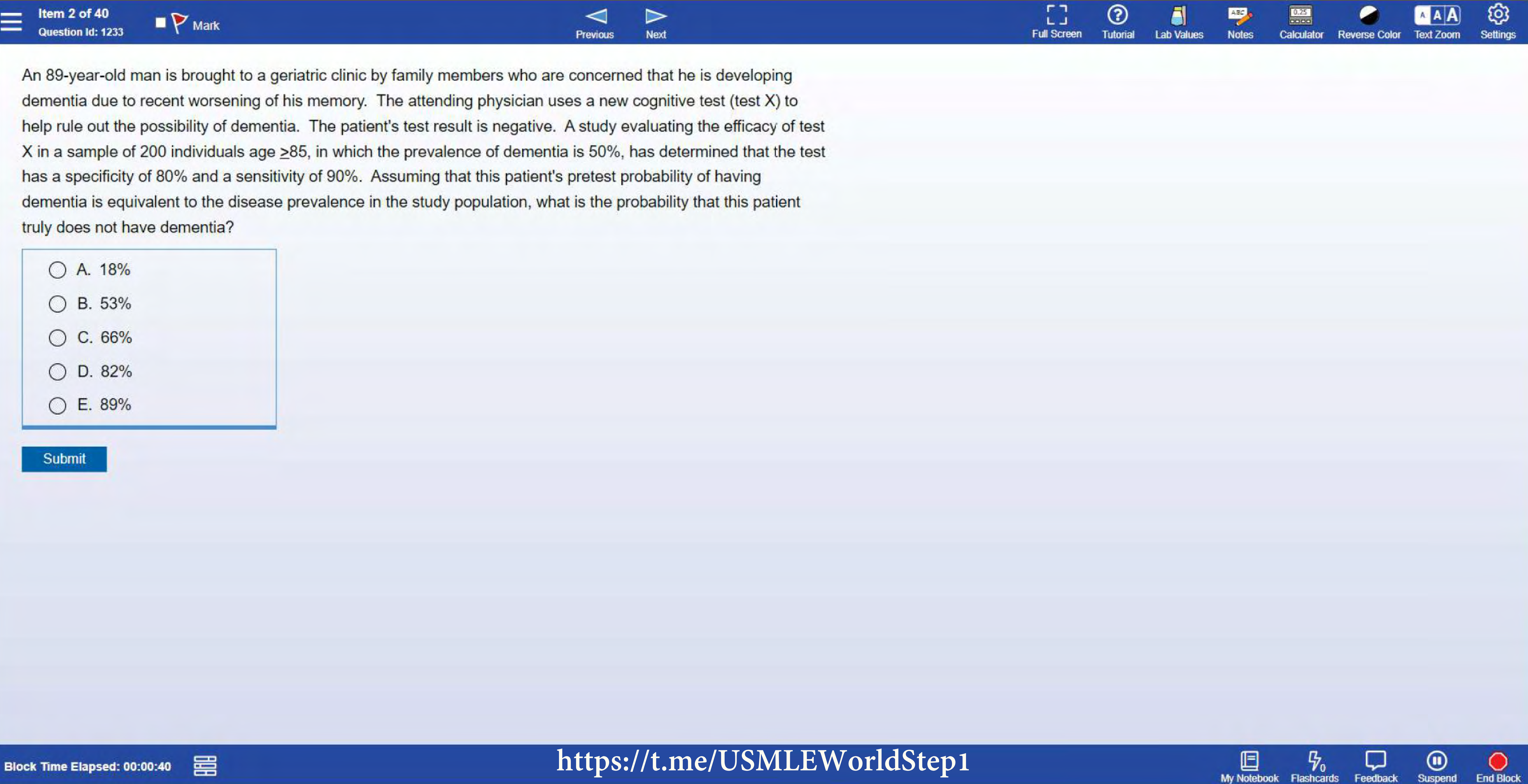
(Choices B and D) The sensitivity of a test refers to its ability to correctly identify individuals with the disease. It is calculated as the number of individuals who have the disease and who test positive (true positives [TP]) divided by the total number of individuals with the disease (TP + false negatives [FN]): sensitivity = TP / (TP + FN). In this example, 90 of 100 liver cancer patients had an abnormally high plasma Hsp90α level (ie, tested positive); therefore, TP = 90 and FN = 10 (ie, 100 − 90). Accordingly, the sensitivity of the test is 90 / (90 + 10) = 90 / 100 = 0.90 (or 90%). Sensitivity is related to the false negative rate (FNR): FNR = 1 – sensitivity. FNR is the probability of a negative test result in a patient with the disease (ie, FN): FNR = FN / (TP + FN) = 10 / (10 + 90) = 10 / 100 = 0.10 (or 10%).

(Choice C) In this example, 33% represents the proportion of study participants with liver cancer: 100 liver cancer patients / (100 liver cancer patients + 200 health controls) = 0.333 (or 33.3%).

Educational objective:

The specificity of a test is its ability to correctly identify individuals without the disease. Specificity can be calculated as follows:

Specificity = True negatives / (True negatives + False positives)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An 89-year-old man is brought to a geriatric clinic by family members who are concerned that he is developing dementia due to recent worsening of his memory. The attending physician uses a new cognitive test (test X) to help rule out the possibility of dementia. The patient's test result is negative. A study evaluating the efficacy of test X in a sample of 200 individuals age $\geq$85, in which the prevalence of dementia is 50%, has determined that the test has a specificity of 80% and a sensitivity of 90%. Assuming that this patient's pretest probability of having dementia is equivalent to the disease prevalence in the study population, what is the probability that this patient truly does not have dementia?

○ A. 18%
○ B. 53%
○ C. 66%
○ D. 82%
○ E. 89%

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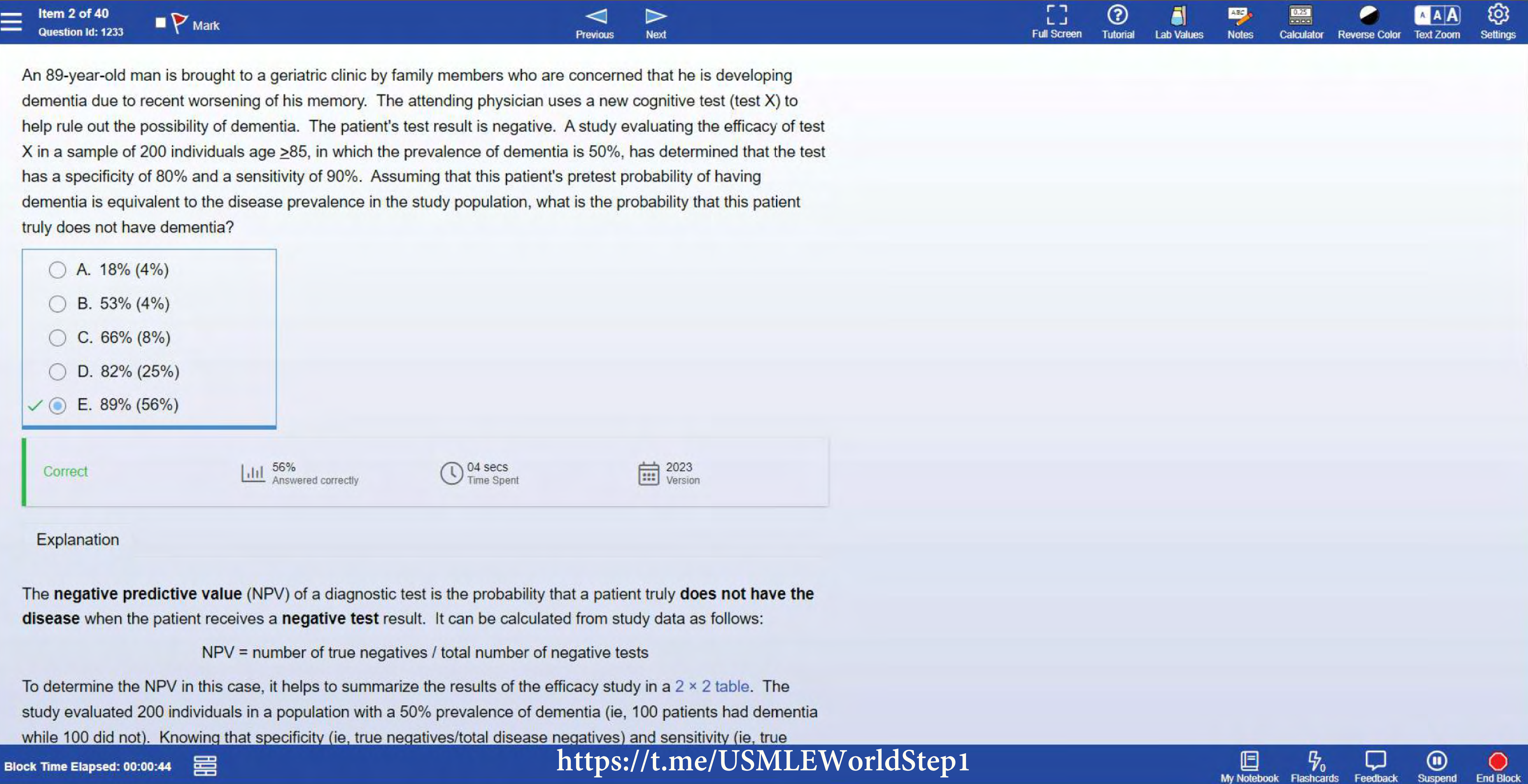
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An 89-year-old man is brought to a geriatric clinic by family members who are concerned that he is developing dementia due to recent worsening of his memory. The attending physician uses a new cognitive test (test X) to help rule out the possibility of dementia. The patient's test result is negative. A study evaluating the efficacy of test X in a sample of 200 individuals age ≥85, in which the prevalence of dementia is 50%, has determined that the test has a specificity of 80% and a sensitivity of 90%. Assuming that this patient's pretest probability of having dementia is equivalent to the disease prevalence in the study population, what is the probability that this patient truly does not have dementia?

- ○ A. 18% (4%)
- ○ B. 53% (4%)
- ○ C. 66% (8%)
- ○ D. 82% (25%)
- ✓ ● E. 89% (56%)

Correct

56% Answered correctly

04 secs Time Spent

2023 Version

Explanation

The **negative predictive value** (NPV) of a diagnostic test is the probability that a patient truly **does not have the disease** when the patient receives a **negative test** result. It can be calculated from study data as follows:

NPV = number of true negatives / total number of negative tests

To determine the NPV in this case, it helps to summarize the results of the efficacy study in a 2 × 2 table. The study evaluated 200 individuals in a population with a 50% prevalence of dementia (ie, 100 patients had dementia while 100 did not). Knowing that specificity (ie, true negatives/total disease negatives) and sensitivity (ie, true

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Correct

Answered correctly

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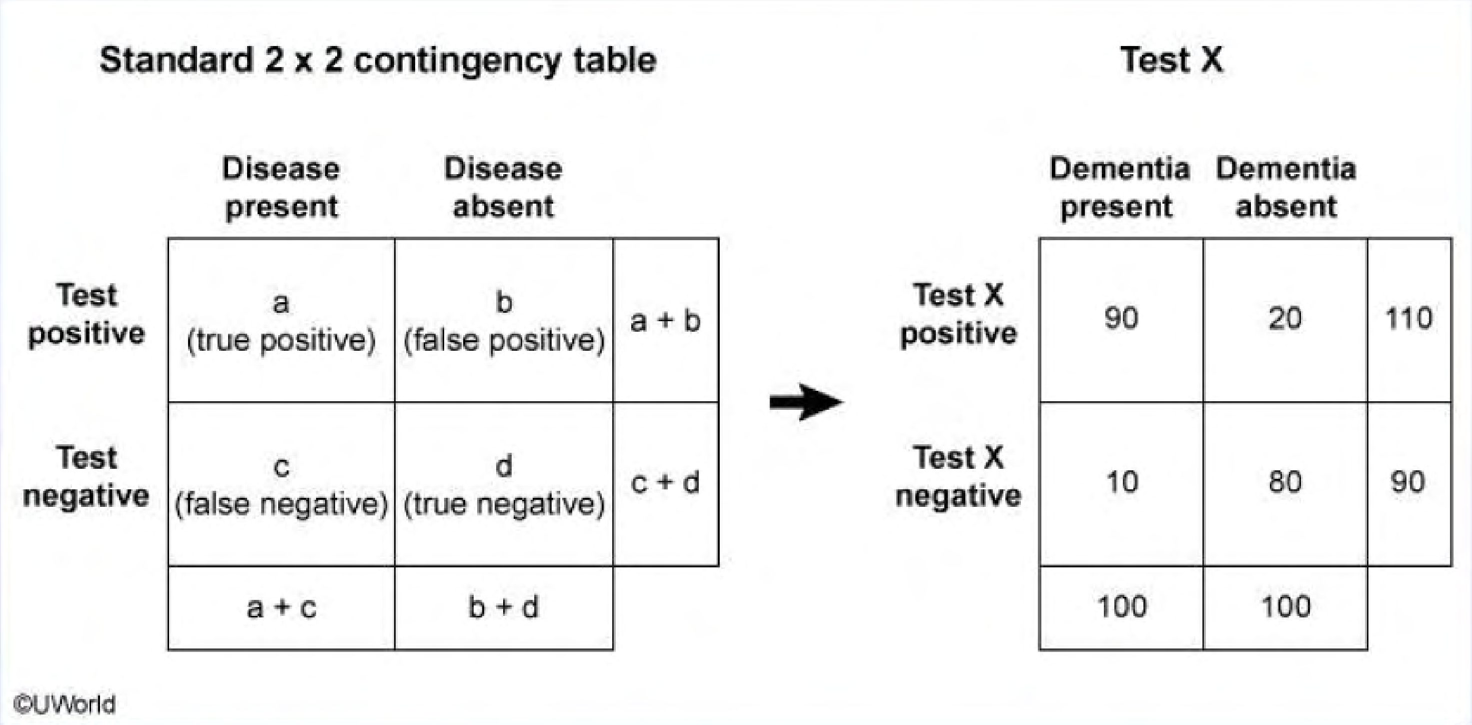
Version

Explanation

The **negative predictive value** (NPV) of a diagnostic test is the probability that a patient truly **does not have the disease** when the patient receives a **negative test** result. It can be calculated from study data as follows:

NPV = number of true negatives / total number of negative tests

To determine the NPV in this case, it helps to summarize the results of the efficacy study in a 2 × 2 table. The study evaluated 200 individuals in a population with a 50% prevalence of dementia (ie, 100 patients had dementia while 100 did not). Knowing that specificity (ie, true negatives/total disease negatives) and sensitivity (ie, true positives/total disease positives) are 80% and 90%, respectively, the following 2 × 2 table can be created:



Standard 2 x 2 contingency table

	Disease present	Disease absent	
Test positive	a (true positive)	b (false positive)	a + b
Test negative	c (false negative)	d (true negative)	c + d
	a + c	b + d	

Test X

	Dementia present	Dementia absent	
Test X positive	90	20	110
Test X negative	10	80	90
	100	100	

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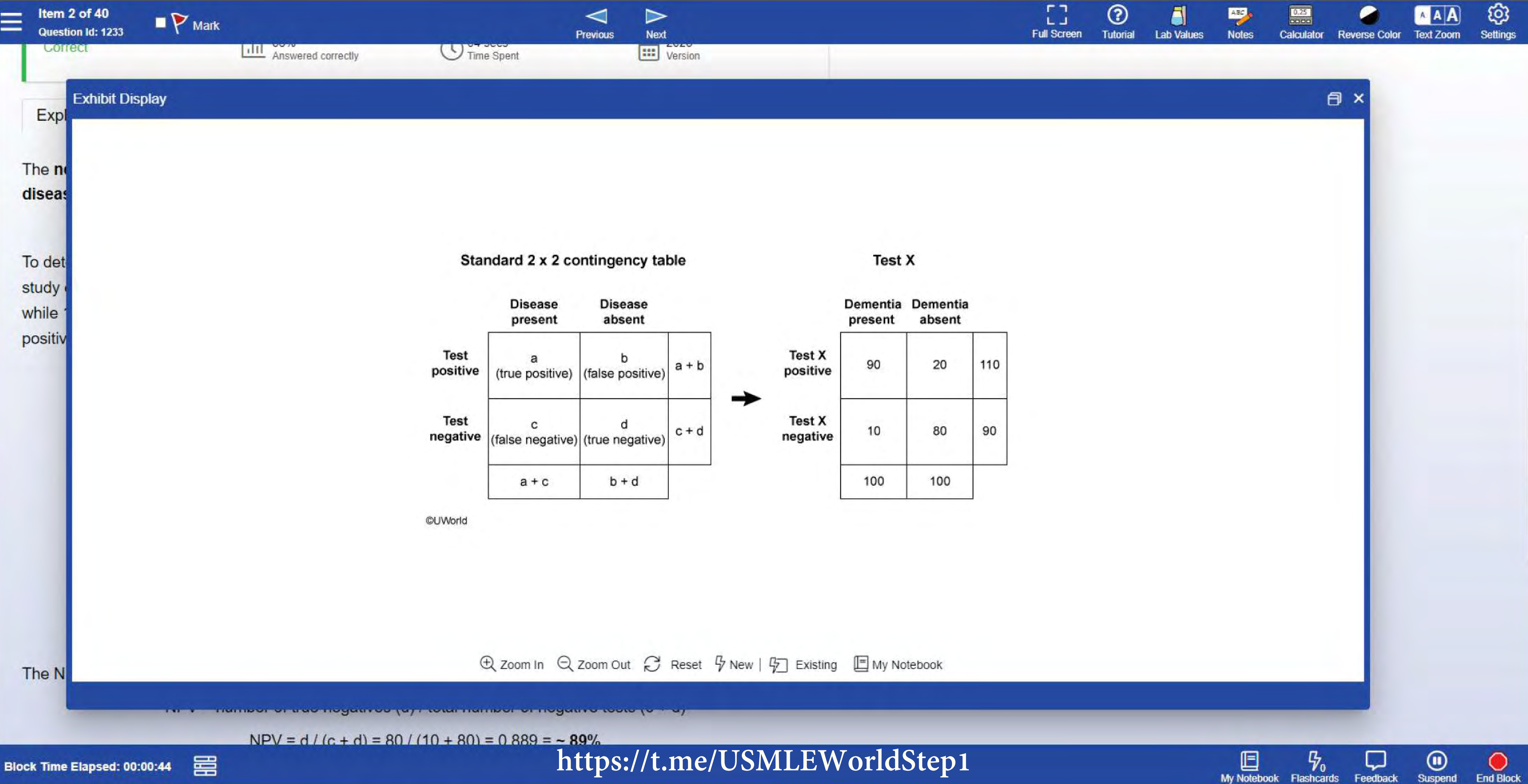
The NPV can now be estimated as follows:

NPV = number of true negatives (d) / total number of negative tests (c + d)

NPV = d / (c + d) = 80 / (10 + 80) = 0.889 = **~ 89%**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Standard 2 x 2 contingency table

	Disease present	Disease absent	
Test positive	a (true positive)	b (false positive)	a + b
Test negative	c (false negative)	d (true negative)	c + d
	a + c	b + d	

→

Test X

	Dementia present	Dementia absent	
Test X positive	90	20	110
Test X negative	10	80	90
	100	100	

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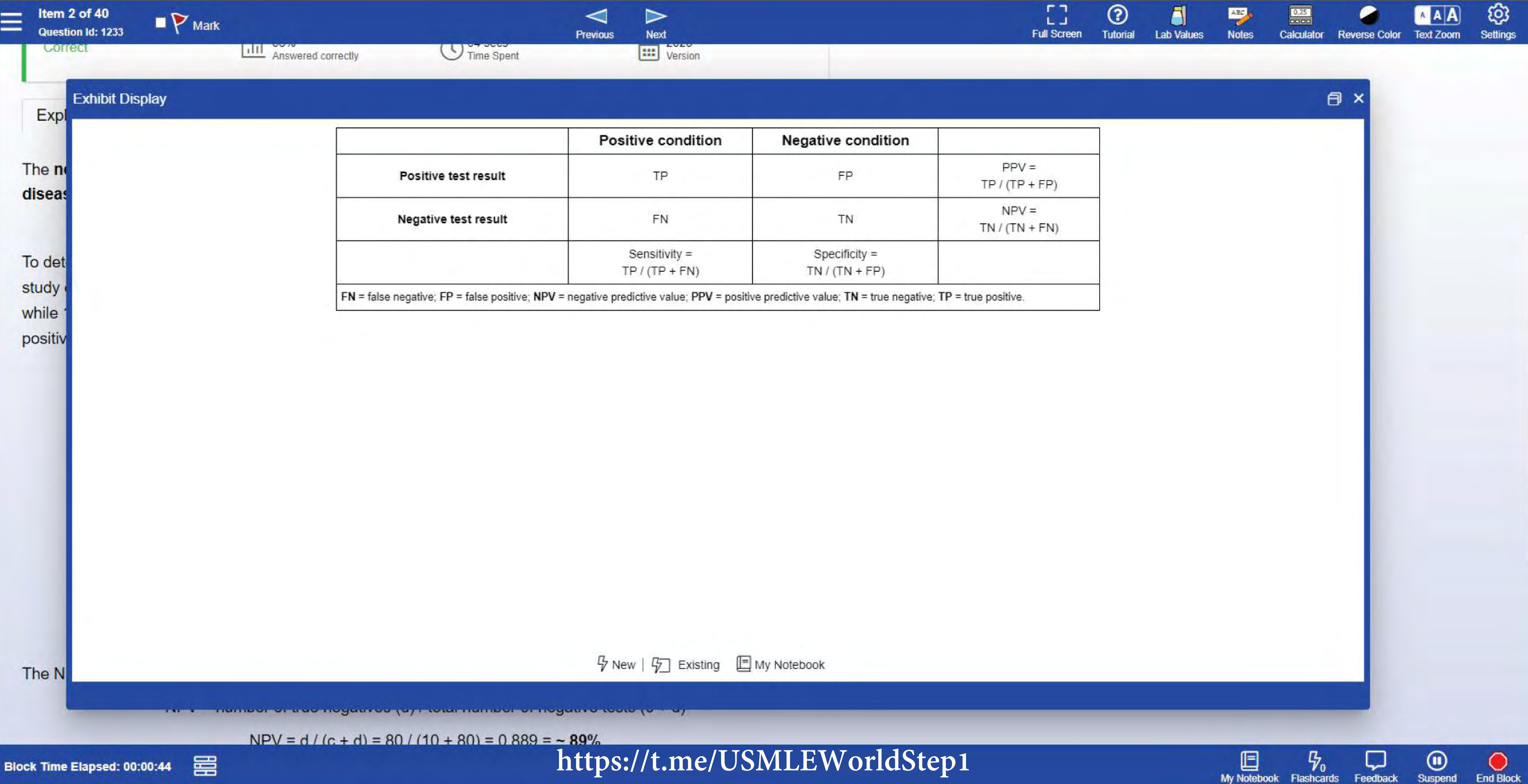
NPV = d / (c + d) = 80 / (10 + 80) = 0.889 = ~ **89%**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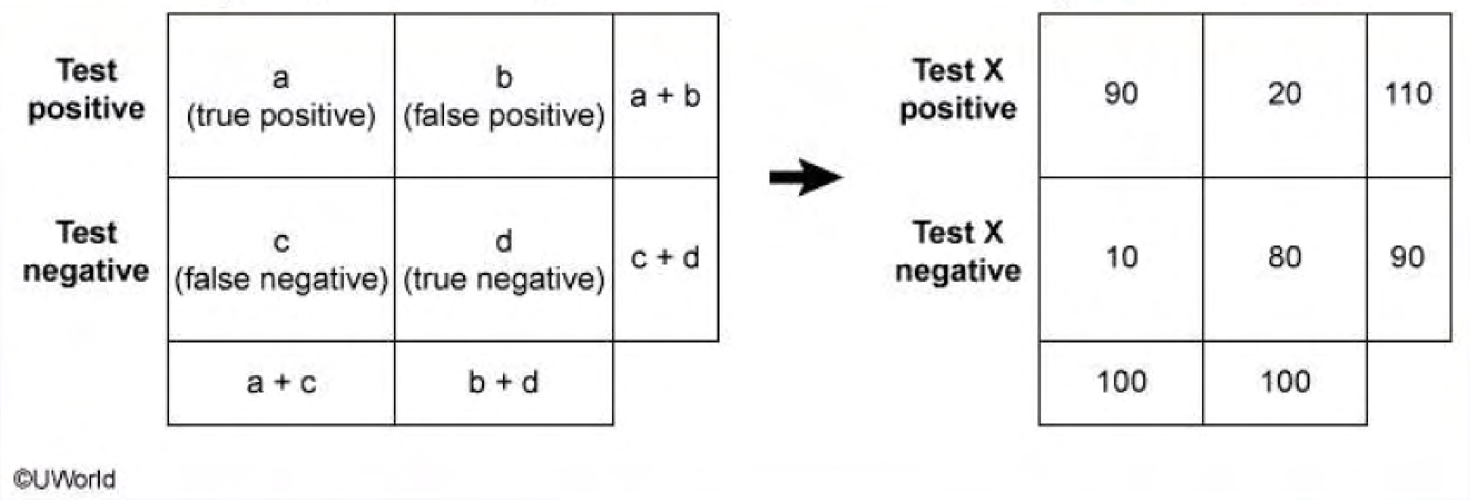
	Positive condition	Negative condition	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

NPV = d / (c + d) = 80 / (10 + 80) = 0.889 = ~ **89%**



Test positive	a (true positive)	b (false positive)	a + b
Test negative	c (false negative)	d (true negative)	c + d
	a + c	b + d	

→

Test X positive	90	20	110
Test X negative	10	80	90
	100	100	

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The NPV can now be estimated as follows:

NPV = number of true negatives (d) / total number of negative tests (c + d)

NPV = d / (c + d) = 80 / (10 + 80) = 0.889 = ~ **89%**

Unlike sensitivity and specificity, positive and negative predictive values vary based on the prevalence of the disease. In fact, the NPV is inversely proportional to the prevalence of a disease (eg, NPV ↓ as disease prevalence ↑). For the NPV to be applicable to an individual patient, that patient's **pretest probability** (eg, probability of having the disease before testing) must be **similar** to the **prevalence of disease** in the population where the study was conducted. The question says to assume that the patient's pretest probability is equivalent to the disease prevalence in the study population, so the NPV calculated in the study is generalizable to this patient.

Educational objective:

Negative predictive value (NPV) represents the probability of not having a disease given a negative test result. NPV is inversely proportional to the prevalence of a disease. When a patient has characteristics similar to the overall population (eg, age, sex, risk factor status), the disease prevalence is a valid estimate of the pretest probability of disease.

Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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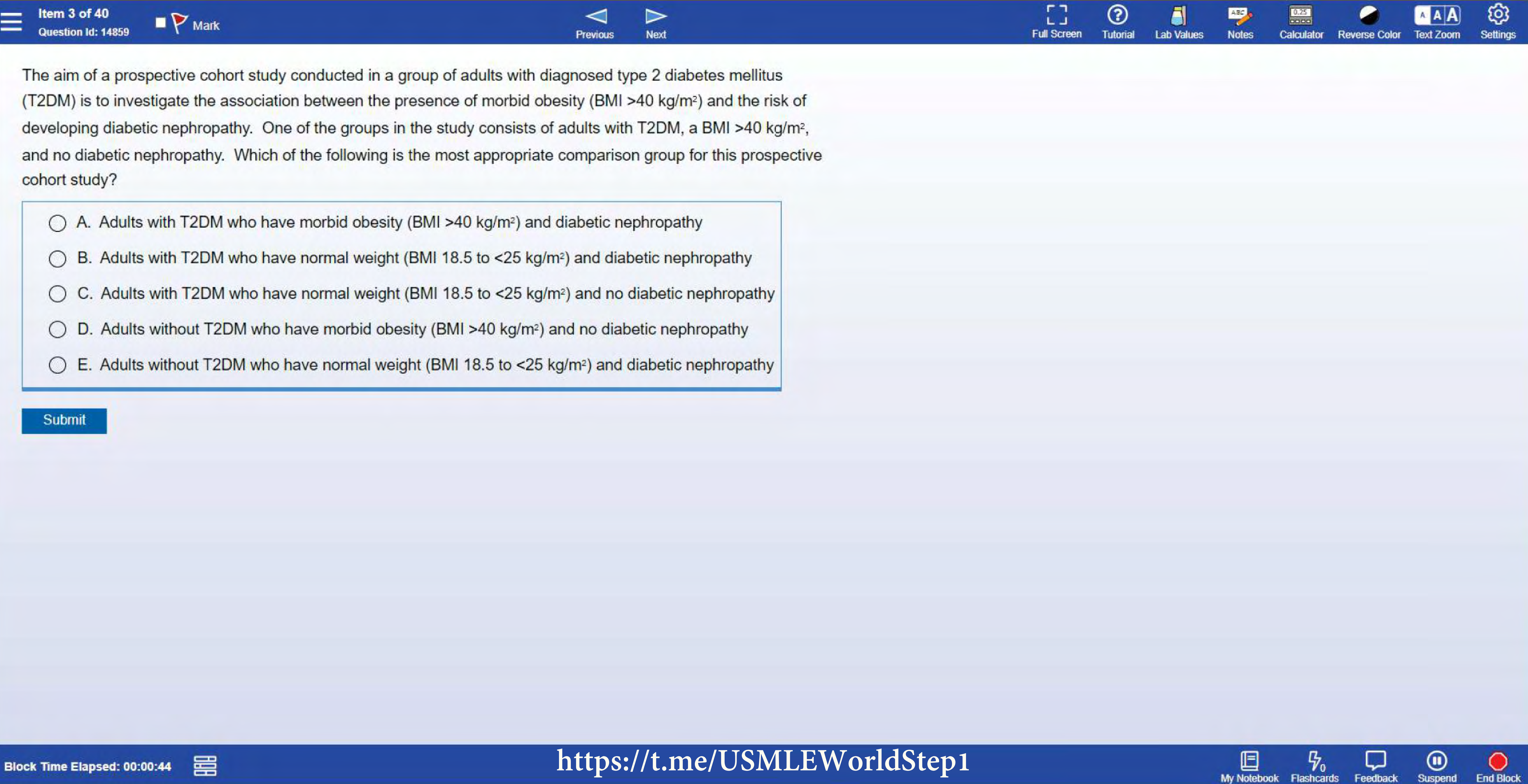
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The aim of a prospective cohort study conducted in a group of adults with diagnosed type 2 diabetes mellitus (T2DM) is to investigate the association between the presence of morbid obesity (BMI >40 kg/m^2) and the risk of developing diabetic nephropathy. One of the groups in the study consists of adults with T2DM, a BMI >40 kg/m^2, and no diabetic nephropathy. Which of the following is the most appropriate comparison group for this prospective cohort study?

○ A. Adults with T2DM who have morbid obesity (BMI >40 kg/m^2) and diabetic nephropathy

○ B. Adults with T2DM who have normal weight (BMI 18.5 to <25 kg/m^2) and diabetic nephropathy

○ C. Adults with T2DM who have normal weight (BMI 18.5 to <25 kg/m^2) and no diabetic nephropathy

○ D. Adults without T2DM who have morbid obesity (BMI >40 kg/m^2) and no diabetic nephropathy

○ E. Adults without T2DM who have normal weight (BMI 18.5 to <25 kg/m^2) and diabetic nephropathy

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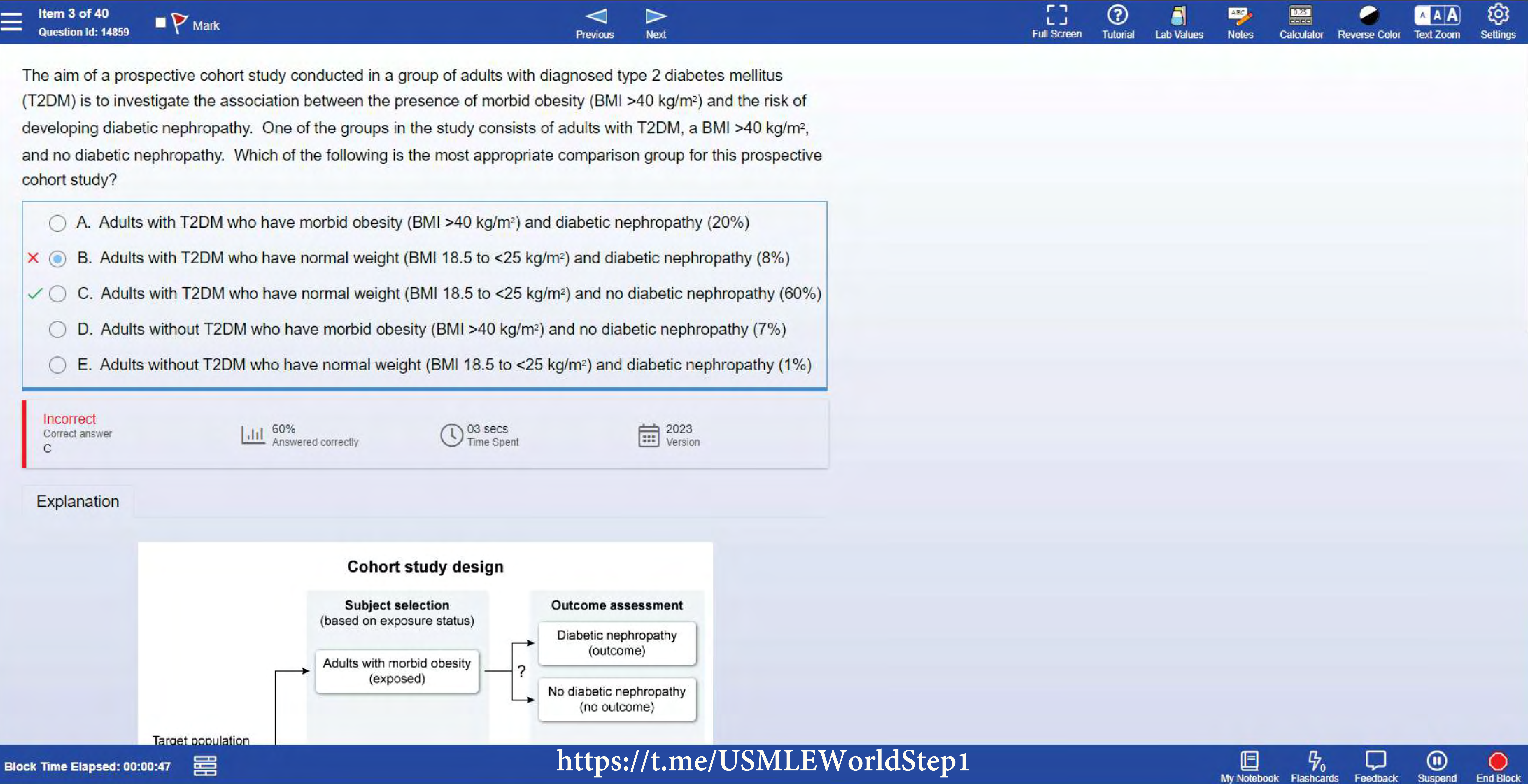
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The aim of a prospective cohort study conducted in a group of adults with diagnosed type 2 diabetes mellitus (T2DM) is to investigate the association between the presence of morbid obesity (BMI >40 kg/m^2) and the risk of developing diabetic nephropathy. One of the groups in the study consists of adults with T2DM, a BMI >40 kg/m^2, and no diabetic nephropathy. Which of the following is the most appropriate comparison group for this prospective cohort study?

- ○ A. Adults with T2DM who have morbid obesity (BMI >40 kg/m^2) and diabetic nephropathy (20%)
- ✗ ● B. Adults with T2DM who have normal weight (BMI 18.5 to <25 kg/m^2) and diabetic nephropathy (8%)
- ✓ ○ C. Adults with T2DM who have normal weight (BMI 18.5 to <25 kg/m^2) and no diabetic nephropathy (60%)
- ○ D. Adults without T2DM who have morbid obesity (BMI >40 kg/m^2) and no diabetic nephropathy (7%)
- ○ E. Adults without T2DM who have normal weight (BMI 18.5 to <25 kg/m^2) and diabetic nephropathy (1%)

Incorrect
Correct answer
C

60%
Answered correctly

03 secs
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2023
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Explanation

Cohort study design

Subject selection
(based on exposure status)
Adults with morbid obesity
(exposed)
?
Outcome assessment
Diabetic nephropathy
(outcome)
No diabetic nephropathy
(no outcome)
Target population

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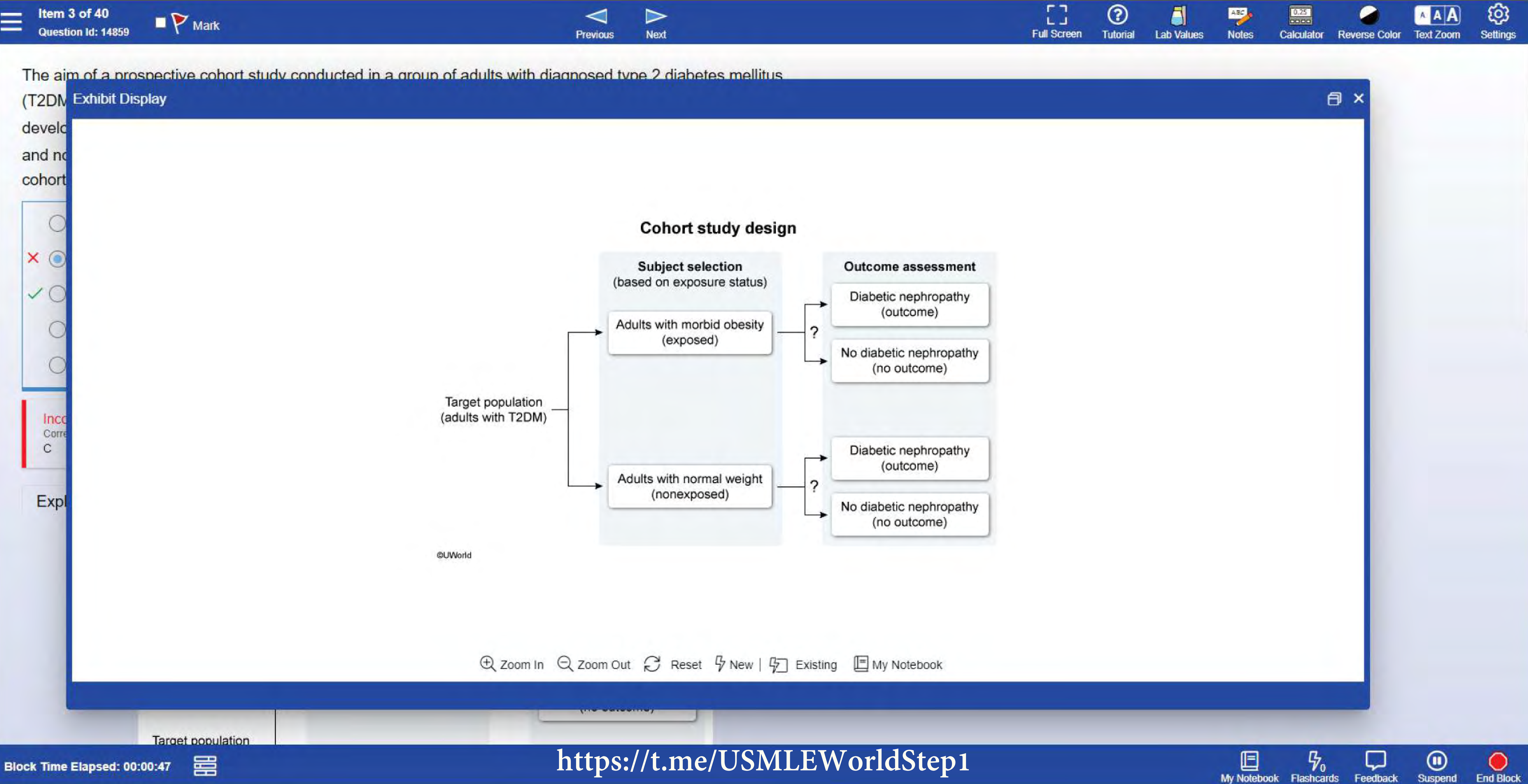
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The aim of a prospective cohort study conducted in a group of adults with diagnosed type 2 diabetes mellitus (T2DM

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Cohort study design

Subject selection
(based on exposure status)

Outcome assessment

Target population (adults with T2DM) → Adults with morbid obesity (exposed) → ? → Diabetic nephropathy (outcome) / No diabetic nephropathy (no outcome)

Target population (adults with T2DM) → Adults with normal weight (nonexposed) → ? → Diabetic nephropathy (outcome) / No diabetic nephropathy (no outcome)

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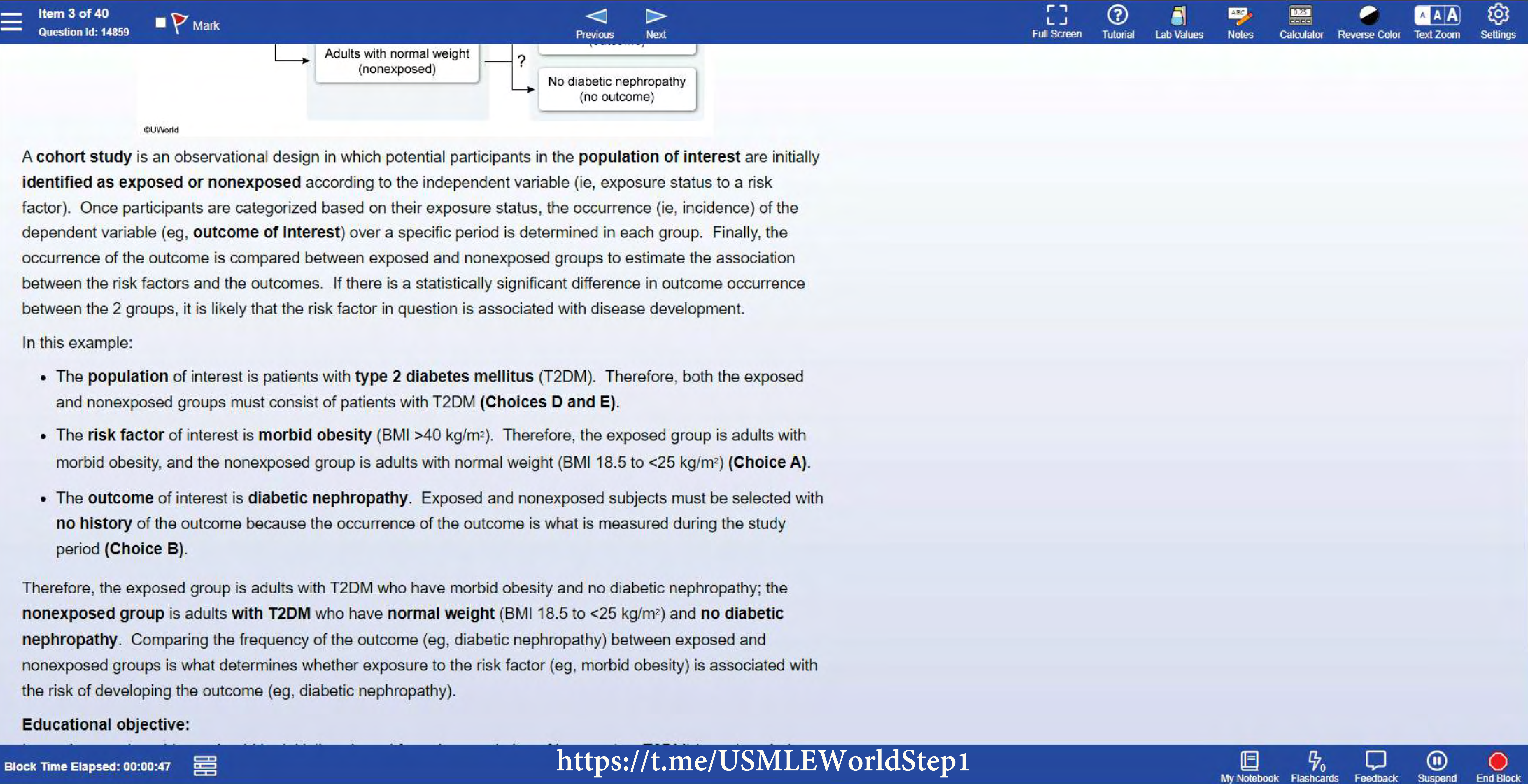
Target population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Adults with normal weight (nonexposed)
?
No diabetic nephropathy (no outcome)
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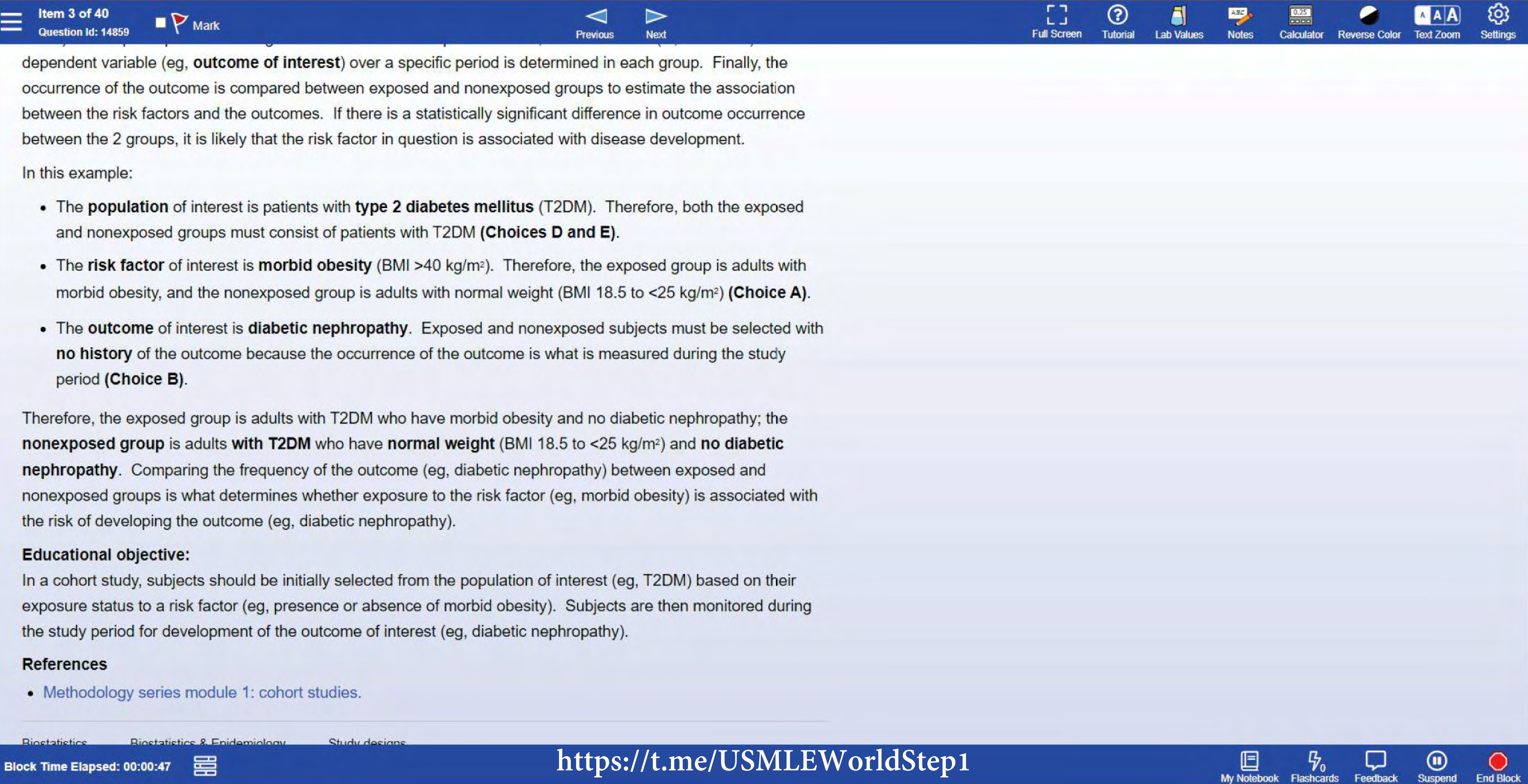
A **cohort study** is an observational design in which potential participants in the **population of interest** are initially **identified as exposed or nonexposed** according to the independent variable (ie, exposure status to a risk factor). Once participants are categorized based on their exposure status, the occurrence (ie, incidence) of the dependent variable (eg, **outcome of interest**) over a specific period is determined in each group. Finally, the occurrence of the outcome is compared between exposed and nonexposed groups to estimate the association between the risk factors and the outcomes. If there is a statistically significant difference in outcome occurrence between the 2 groups, it is likely that the risk factor in question is associated with disease development.

In this example:

- The **population** of interest is patients with **type 2 diabetes mellitus** (T2DM). Therefore, both the exposed and nonexposed groups must consist of patients with T2DM **(Choices D and E)**.
- The **risk factor** of interest is **morbid obesity** (BMI >40 kg/m^2). Therefore, the exposed group is adults with morbid obesity, and the nonexposed group is adults with normal weight (BMI 18.5 to <25 kg/m^2) **(Choice A)**.
- The **outcome** of interest is **diabetic nephropathy**. Exposed and nonexposed subjects must be selected with **no history** of the outcome because the occurrence of the outcome is what is measured during the study period **(Choice B)**.

Therefore, the exposed group is adults with T2DM who have morbid obesity and no diabetic nephropathy; the **nonexposed group** is adults **with T2DM** who have **normal weight** (BMI 18.5 to <25 kg/m^2) and **no diabetic nephropathy**. Comparing the frequency of the outcome (eg, diabetic nephropathy) between exposed and nonexposed groups is what determines whether exposure to the risk factor (eg, morbid obesity) is associated with the risk of developing the outcome (eg, diabetic nephropathy).

Educational objective:



dependent variable (eg, **outcome of interest**) over a specific period is determined in each group. Finally, the occurrence of the outcome is compared between exposed and nonexposed groups to estimate the association between the risk factors and the outcomes. If there is a statistically significant difference in outcome occurrence between the 2 groups, it is likely that the risk factor in question is associated with disease development.

In this example:

- The **population** of interest is patients with **type 2 diabetes mellitus** (T2DM). Therefore, both the exposed and nonexposed groups must consist of patients with T2DM **(Choices D and E)**.
- The **risk factor** of interest is **morbid obesity** (BMI >40 kg/m^2). Therefore, the exposed group is adults with morbid obesity, and the nonexposed group is adults with normal weight (BMI 18.5 to <25 kg/m^2) **(Choice A)**.
- The **outcome** of interest is **diabetic nephropathy**. Exposed and nonexposed subjects must be selected with **no history** of the outcome because the occurrence of the outcome is what is measured during the study period **(Choice B)**.

Therefore, the exposed group is adults with T2DM who have morbid obesity and no diabetic nephropathy; the **nonexposed group** is adults **with T2DM** who have **normal weight** (BMI 18.5 to <25 kg/m^2) and **no diabetic nephropathy**. Comparing the frequency of the outcome (eg, diabetic nephropathy) between exposed and nonexposed groups is what determines whether exposure to the risk factor (eg, morbid obesity) is associated with the risk of developing the outcome (eg, diabetic nephropathy).

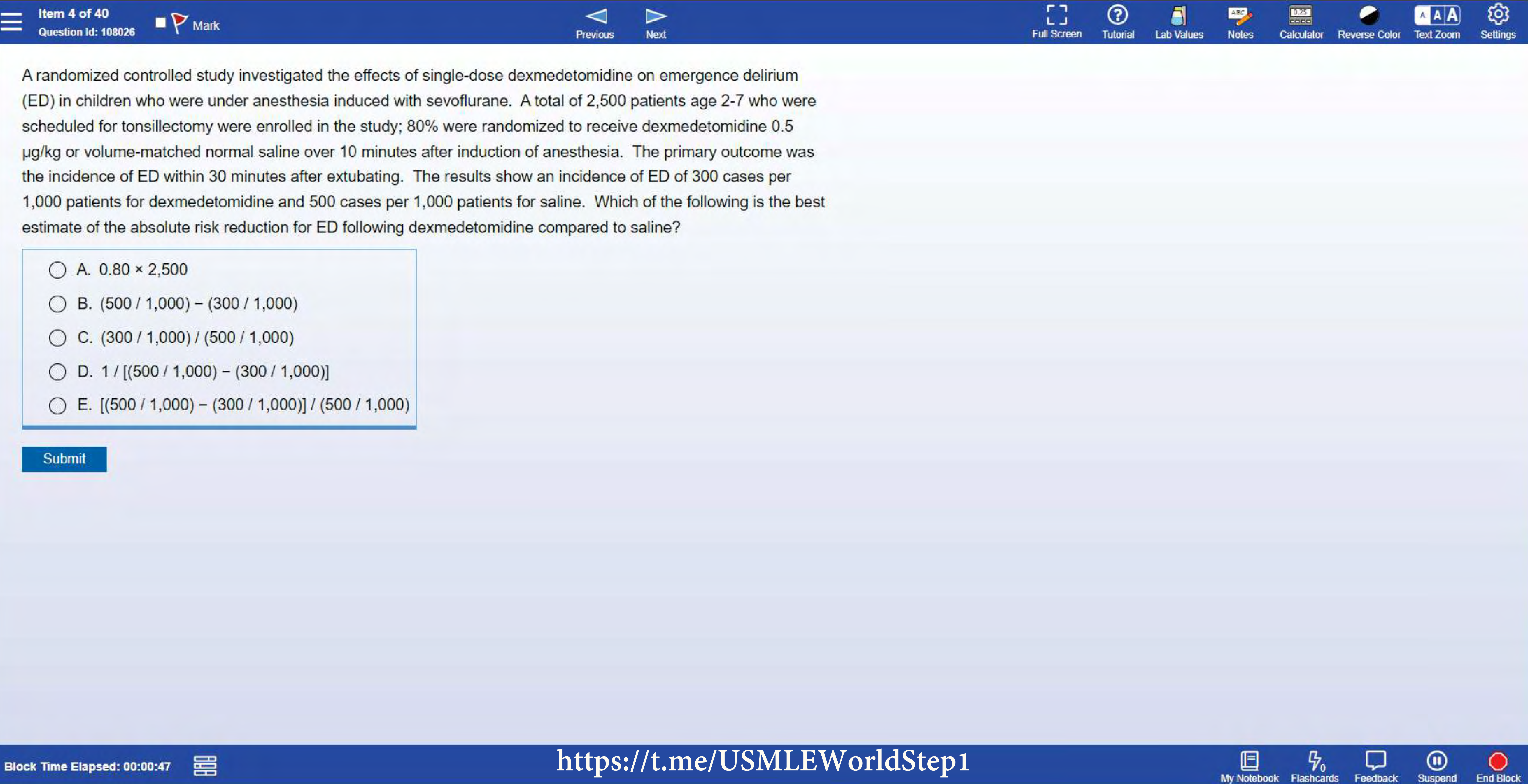
Educational objective:

In a cohort study, subjects should be initially selected from the population of interest (eg, T2DM) based on their exposure status to a risk factor (eg, presence or absence of morbid obesity). Subjects are then monitored during the study period for development of the outcome of interest (eg, diabetic nephropathy).

References

- Methodology series module 1: cohort studies.

Biostatistics Biostatistics & Epidemiology Study designs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A randomized controlled study investigated the effects of single-dose dexmedetomidine on emergence delirium (ED) in children who were under anesthesia induced with sevoflurane. A total of 2,500 patients age 2-7 who were scheduled for tonsillectomy were enrolled in the study; 80% were randomized to receive dexmedetomidine 0.5 µg/kg or volume-matched normal saline over 10 minutes after induction of anesthesia. The primary outcome was the incidence of ED within 30 minutes after extubating. The results show an incidence of ED of 300 cases per 1,000 patients for dexmedetomidine and 500 cases per 1,000 patients for saline. Which of the following is the best estimate of the absolute risk reduction for ED following dexmedetomidine compared to saline?

○ A. 0.80 × 2,500
○ B. (500 / 1,000) – (300 / 1,000)
○ C. (300 / 1,000) / (500 / 1,000)
○ D. 1 / [(500 / 1,000) – (300 / 1,000)]
○ E. [(500 / 1,000) – (300 / 1,000)] / (500 / 1,000)

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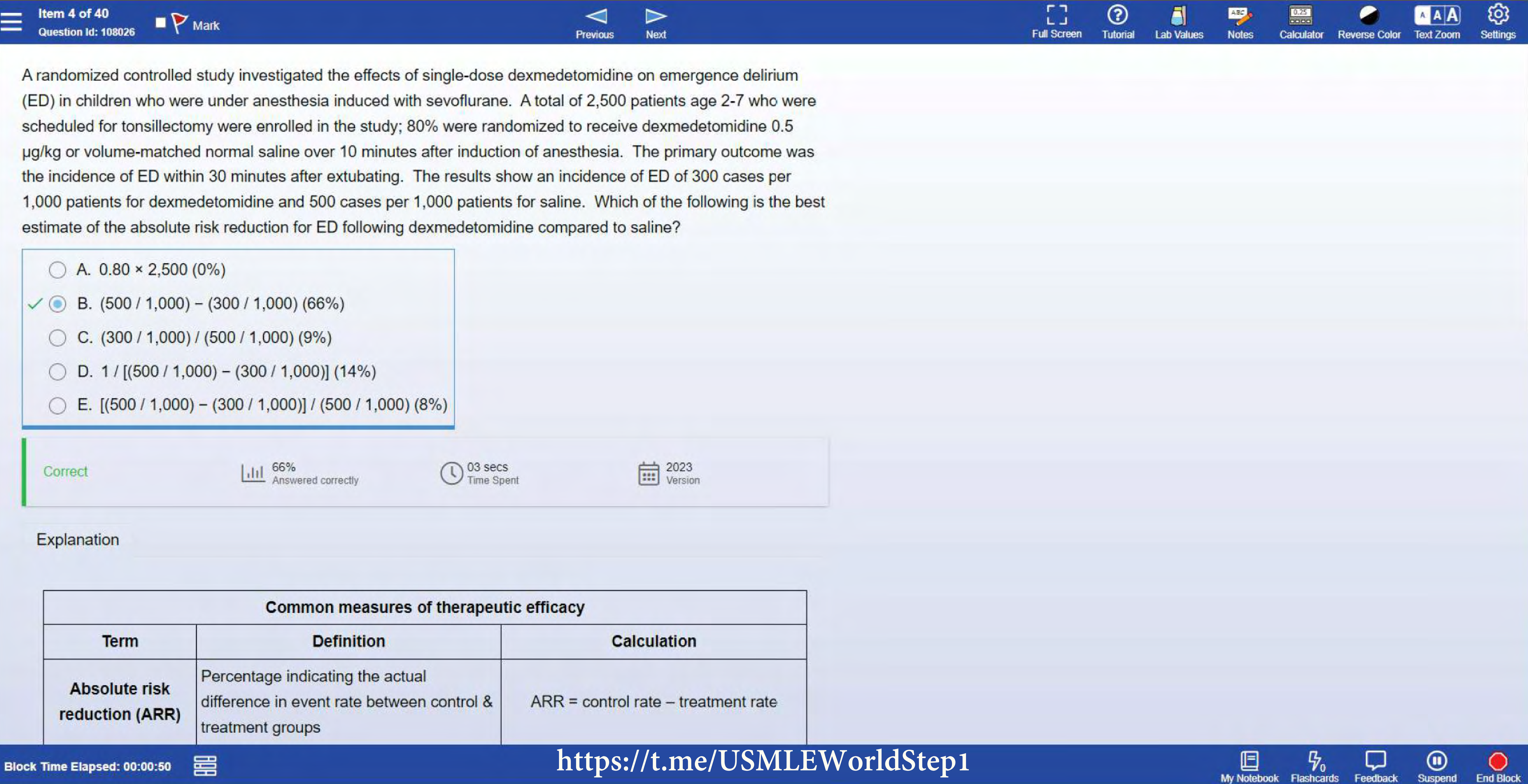
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○ A. 0.80 × 2,500 (0%)

✓ ● B. (500 / 1,000) – (300 / 1,000) (66%)

○ C. (300 / 1,000) / (500 / 1,000) (9%)

○ D. 1 / [(500 / 1,000) – (300 / 1,000)] (14%)

○ E. [(500 / 1,000) – (300 / 1,000)] / (500 / 1,000) (8%)

Correct

66%
Answered correctly

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Explanation

Common measures of therapeutic efficacy		
Term	**Definition**	**Calculation**
Absolute risk reduction (ARR)	Percentage indicating the actual difference in event rate between control & treatment groups	ARR = control rate – treatment rate

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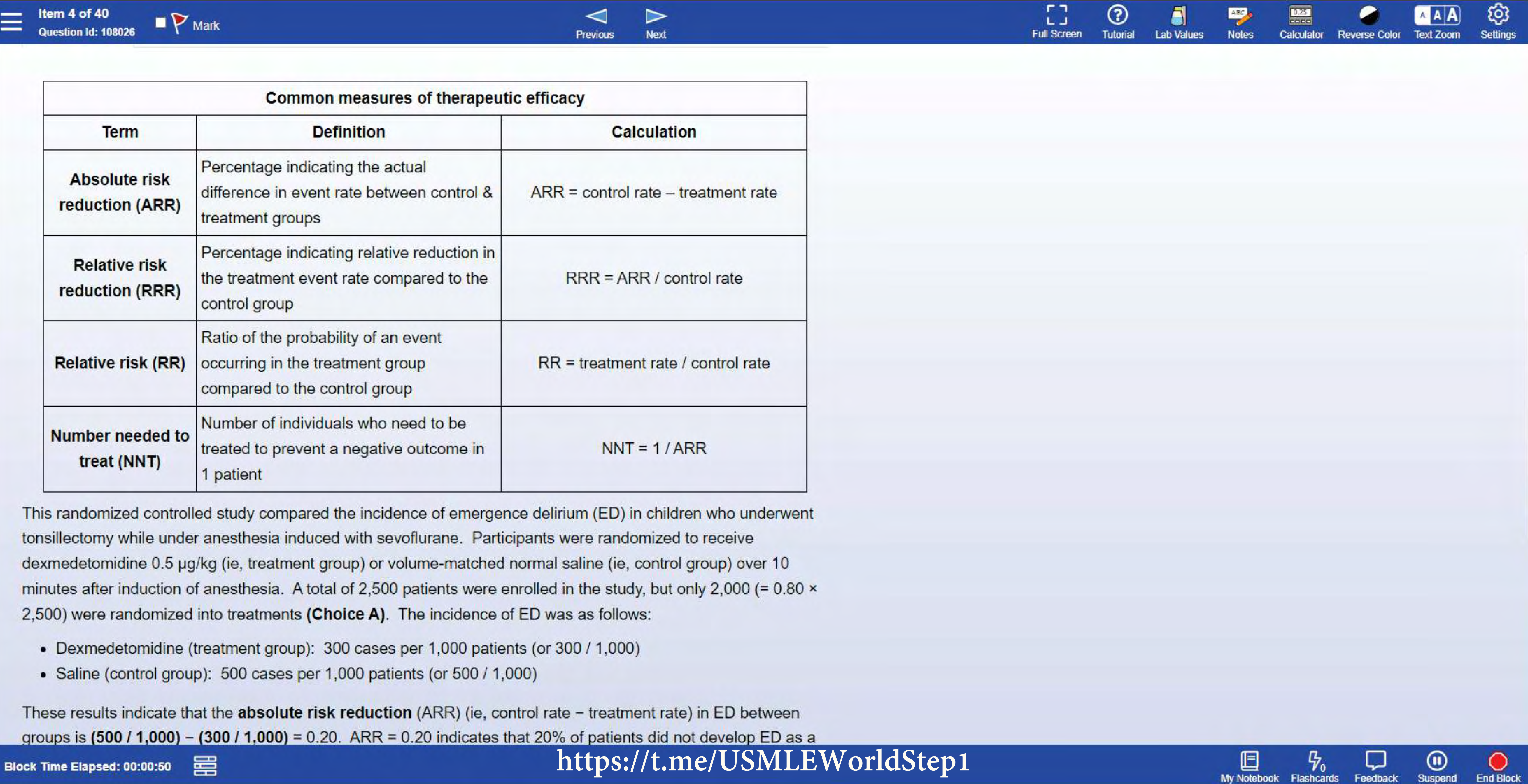
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Common measures of therapeutic efficacy

Term	Definition	Calculation
Absolute risk reduction (ARR)	Percentage indicating the actual difference in event rate between control & treatment groups	ARR = control rate – treatment rate
Relative risk reduction (RRR)	Percentage indicating relative reduction in the treatment event rate compared to the control group	RRR = ARR / control rate
Relative risk (RR)	Ratio of the probability of an event occurring in the treatment group compared to the control group	RR = treatment rate / control rate
Number needed to treat (NNT)	Number of individuals who need to be treated to prevent a negative outcome in 1 patient	NNT = 1 / ARR

This randomized controlled study compared the incidence of emergence delirium (ED) in children who underwent tonsillectomy while under anesthesia induced with sevoflurane. Participants were randomized to receive dexmedetomidine 0.5 µg/kg (ie, treatment group) or volume-matched normal saline (ie, control group) over 10 minutes after induction of anesthesia. A total of 2,500 patients were enrolled in the study, but only 2,000 (= 0.80 × 2,500) were randomized into treatments **(Choice A)**. The incidence of ED was as follows:

- Dexmedetomidine (treatment group): 300 cases per 1,000 patients (or 300 / 1,000)
- Saline (control group): 500 cases per 1,000 patients (or 500 / 1,000)

These results indicate that the **absolute risk reduction** (ARR) (ie, control rate − treatment rate) in ED between groups is **(500 / 1,000)** – **(300 / 1,000)** = 0.20. ARR = 0.20 indicates that 20% of patients did not develop ED as a

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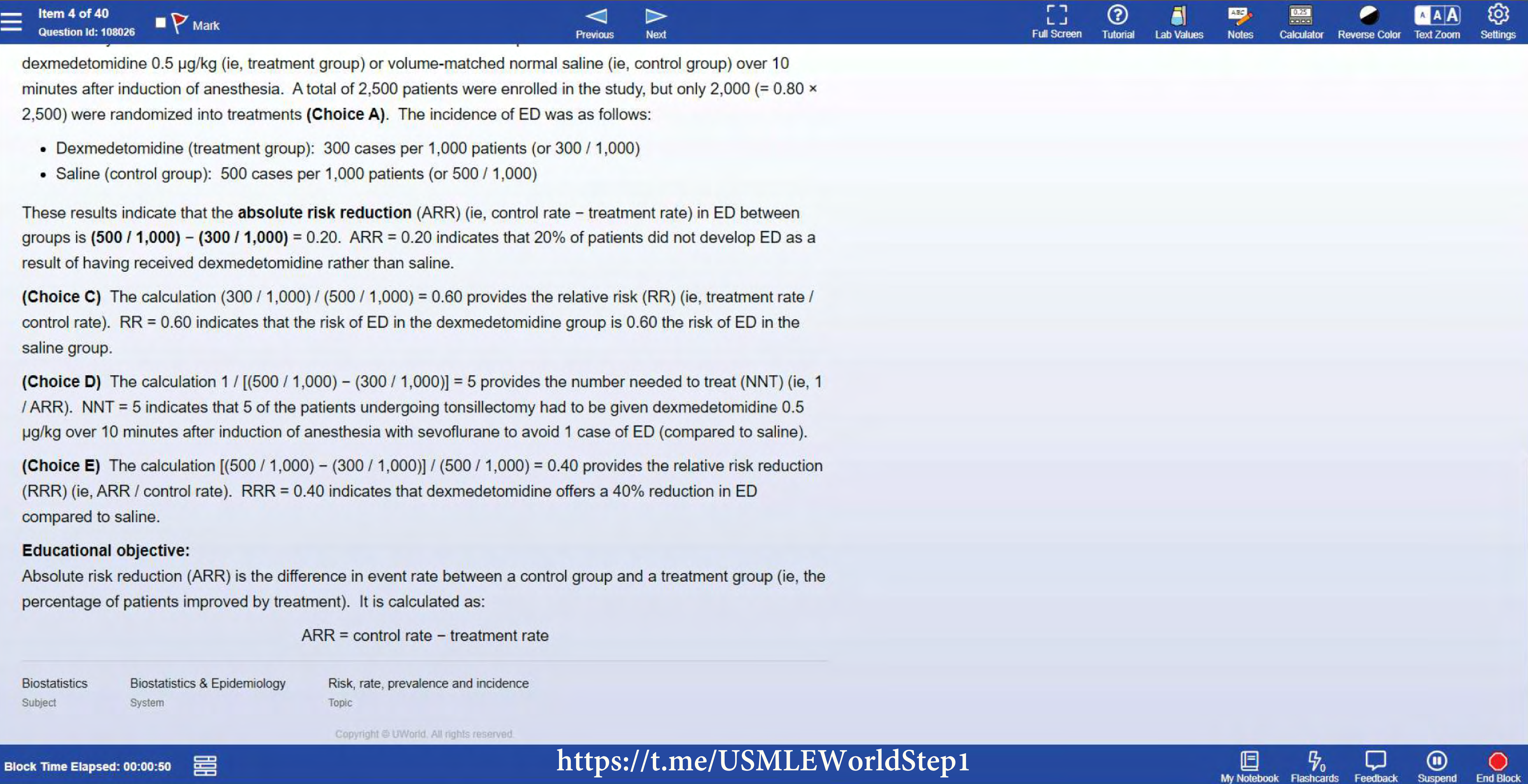
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dexmedetomidine 0.5 μg/kg (ie, treatment group) or volume-matched normal saline (ie, control group) over 10 minutes after induction of anesthesia. A total of 2,500 patients were enrolled in the study, but only 2,000 (= 0.80 × 2,500) were randomized into treatments **(Choice A)**. The incidence of ED was as follows:

- Dexmedetomidine (treatment group): 300 cases per 1,000 patients (or 300 / 1,000)
- Saline (control group): 500 cases per 1,000 patients (or 500 / 1,000)

These results indicate that the **absolute risk reduction** (ARR) (ie, control rate − treatment rate) in ED between groups is **(500 / 1,000) − (300 / 1,000)** = 0.20. ARR = 0.20 indicates that 20% of patients did not develop ED as a result of having received dexmedetomidine rather than saline.

(Choice C) The calculation (300 / 1,000) / (500 / 1,000) = 0.60 provides the relative risk (RR) (ie, treatment rate / control rate). RR = 0.60 indicates that the risk of ED in the dexmedetomidine group is 0.60 the risk of ED in the saline group.

(Choice D) The calculation 1 / [(500 / 1,000) − (300 / 1,000)] = 5 provides the number needed to treat (NNT) (ie, 1 / ARR). NNT = 5 indicates that 5 of the patients undergoing tonsillectomy had to be given dexmedetomidine 0.5 μg/kg over 10 minutes after induction of anesthesia with sevoflurane to avoid 1 case of ED (compared to saline).

(Choice E) The calculation [(500 / 1,000) − (300 / 1,000)] / (500 / 1,000) = 0.40 provides the relative risk reduction (RRR) (ie, ARR / control rate). RRR = 0.40 indicates that dexmedetomidine offers a 40% reduction in ED compared to saline.

Educational objective:

Absolute risk reduction (ARR) is the difference in event rate between a control group and a treatment group (ie, the percentage of patients improved by treatment). It is calculated as:

$$\text{ARR} = \text{control rate} - \text{treatment rate}$$

Biostatistics	Biostatistics & Epidemiology	Risk, rate, prevalence and incidence
Subject	System	Topic

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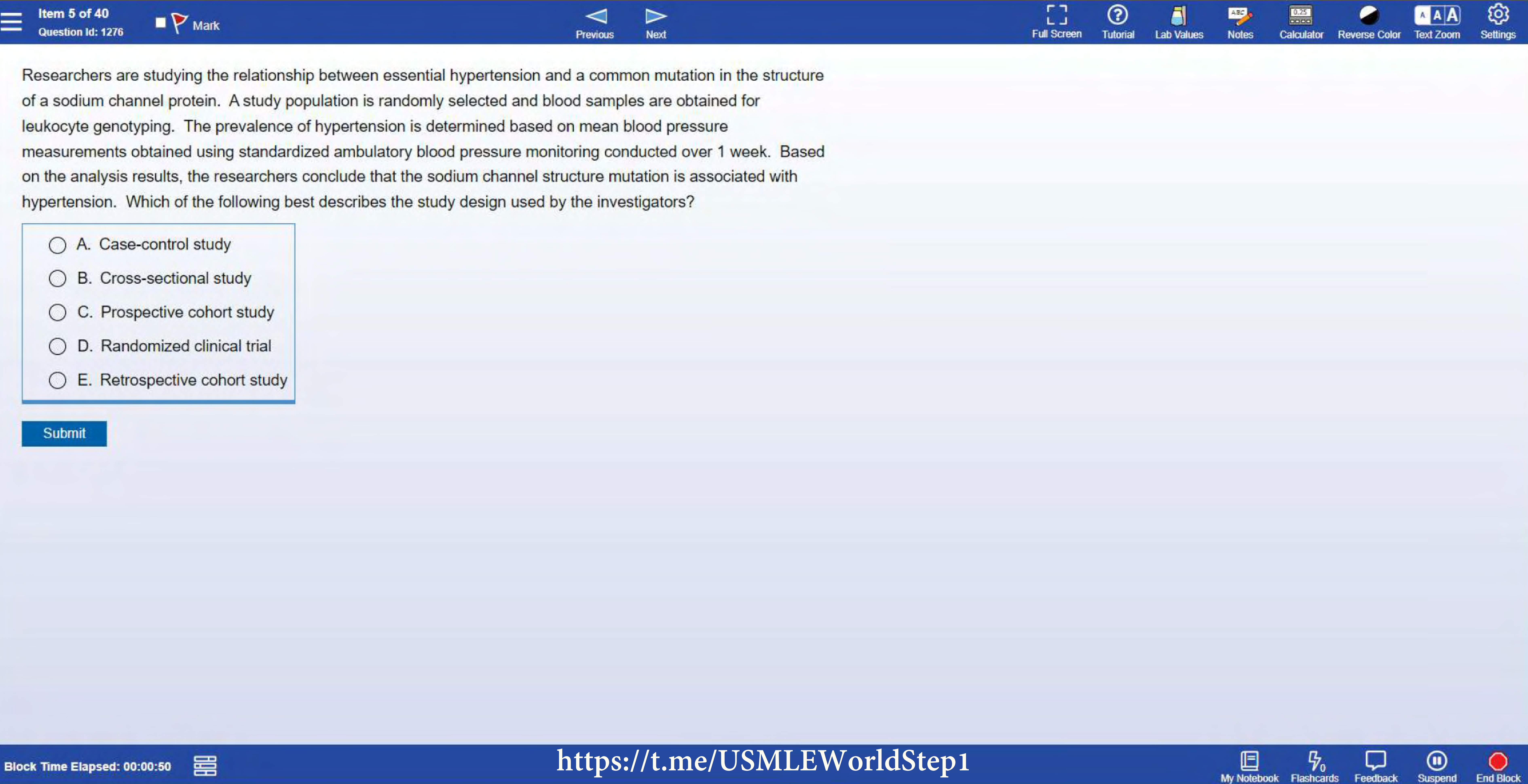
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Question Id: 1276

Researchers are studying the relationship between essential hypertension and a common mutation in the structure of a sodium channel protein. A study population is randomly selected and blood samples are obtained for leukocyte genotyping. The prevalence of hypertension is determined based on mean blood pressure measurements obtained using standardized ambulatory blood pressure monitoring conducted over 1 week. Based on the analysis results, the researchers conclude that the sodium channel structure mutation is associated with hypertension. Which of the following best describes the study design used by the investigators?

○ A. Case-control study
○ B. Cross-sectional study
○ C. Prospective cohort study
○ D. Randomized clinical trial
○ E. Retrospective cohort study

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Researchers are studying the relationship between essential hypertension and a common mutation in the structure of a sodium channel protein. A study population is randomly selected and blood samples are obtained for leukocyte genotyping. The prevalence of hypertension is determined based on mean blood pressure measurements obtained using standardized ambulatory blood pressure monitoring conducted over 1 week. Based on the analysis results, the researchers conclude that the sodium channel structure mutation is associated with hypertension. Which of the following best describes the study design used by the investigators?

- ✗ ● A. Case-control study (10%)
- ✓ ○ B. Cross-sectional study (56%)
- ○ C. Prospective cohort study (17%)
- ○ D. Randomized clinical trial (9%)
- ○ E. Retrospective cohort study (6%)

Incorrect
Correct answer
B

56%
Answered correctly

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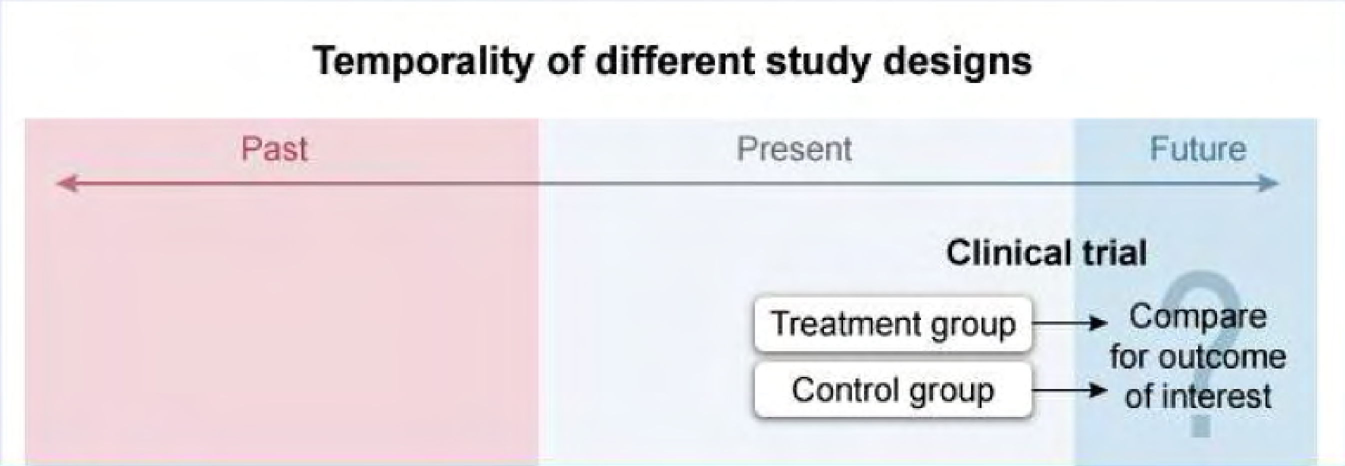
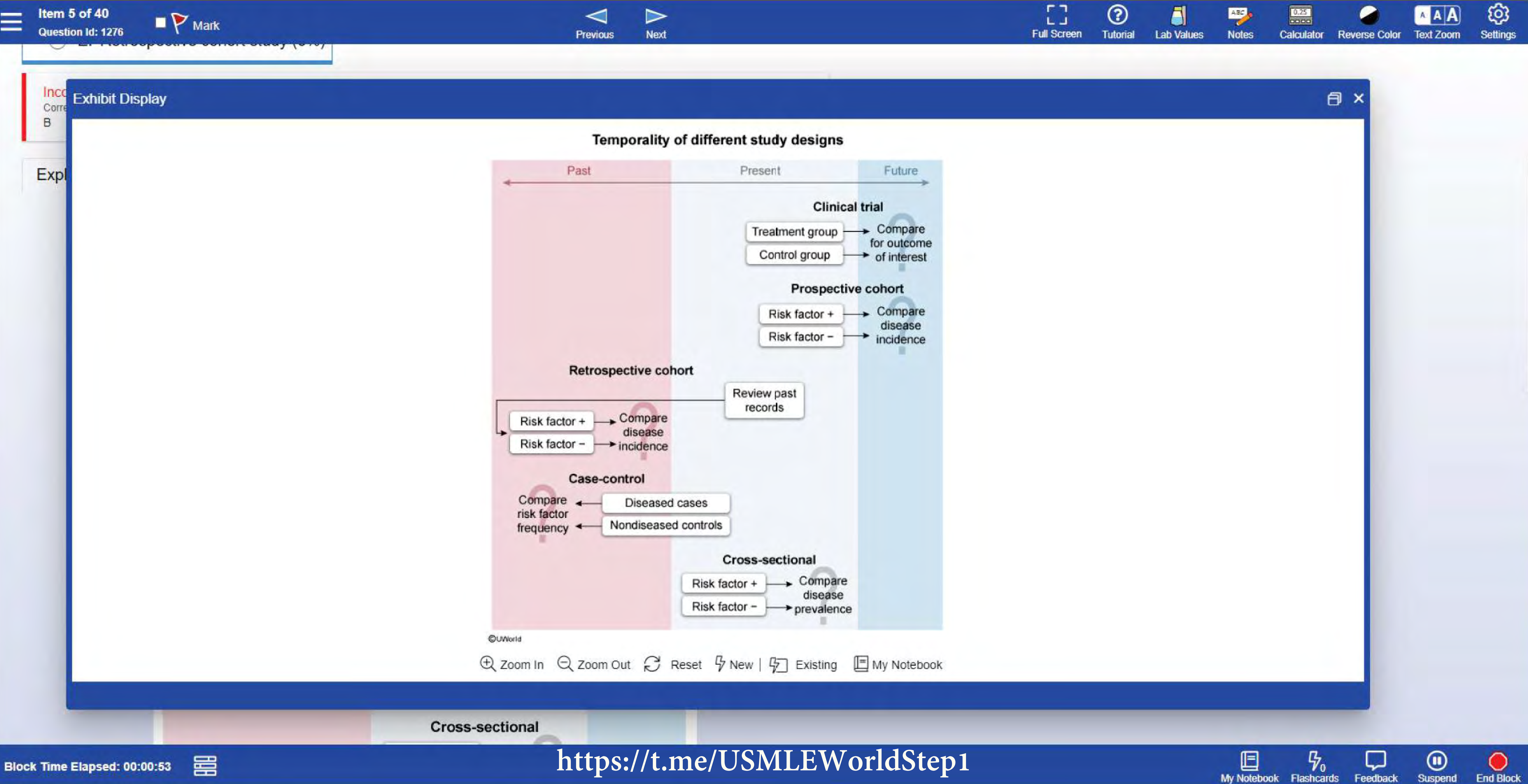
Explanation


Temporality of different study designs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Compare for outcome of interest
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Compare disease incidence
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Review past records
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Compare risk factor frequency
Diseased cases
Nondiseased controls
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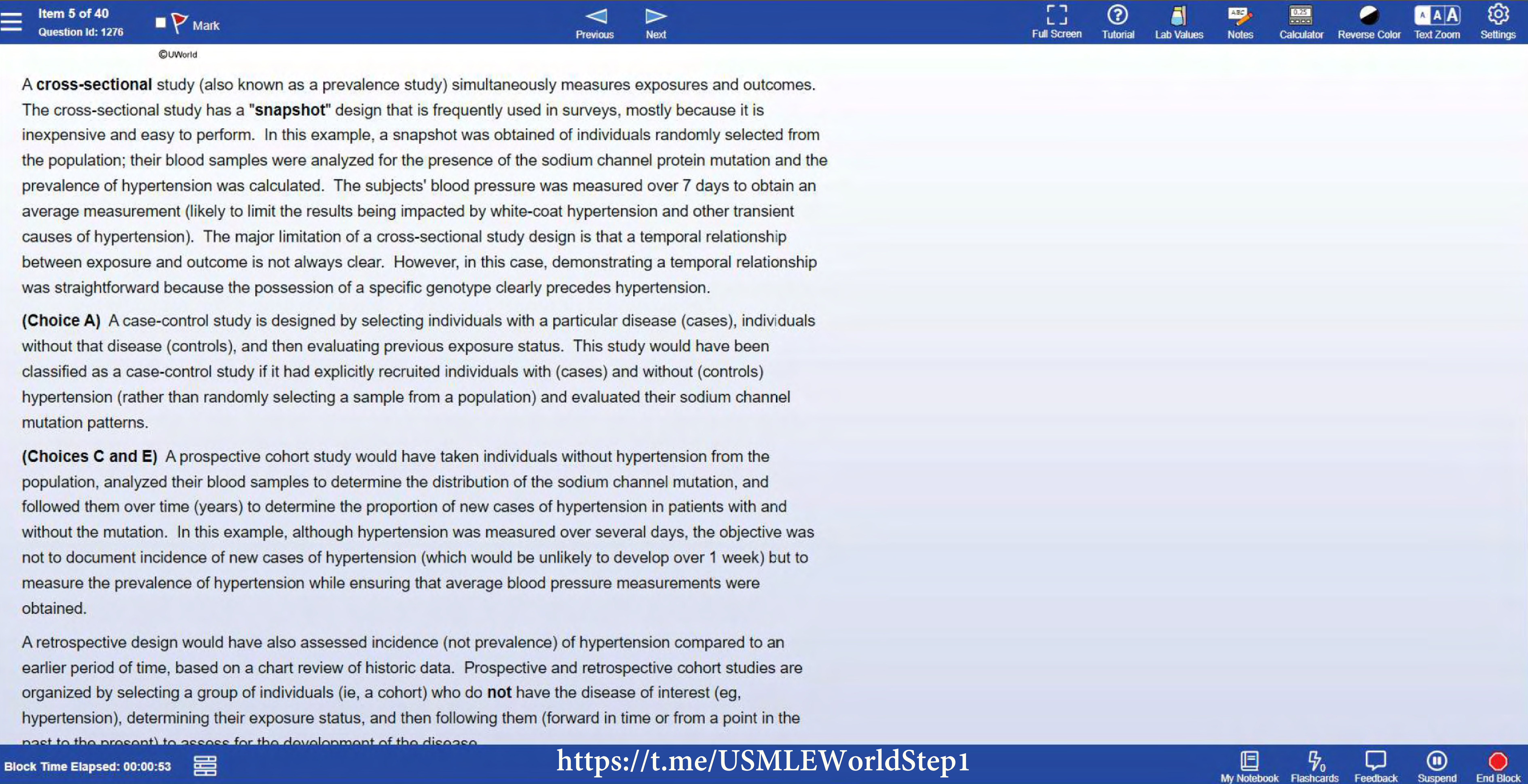
Temporality of different study designs

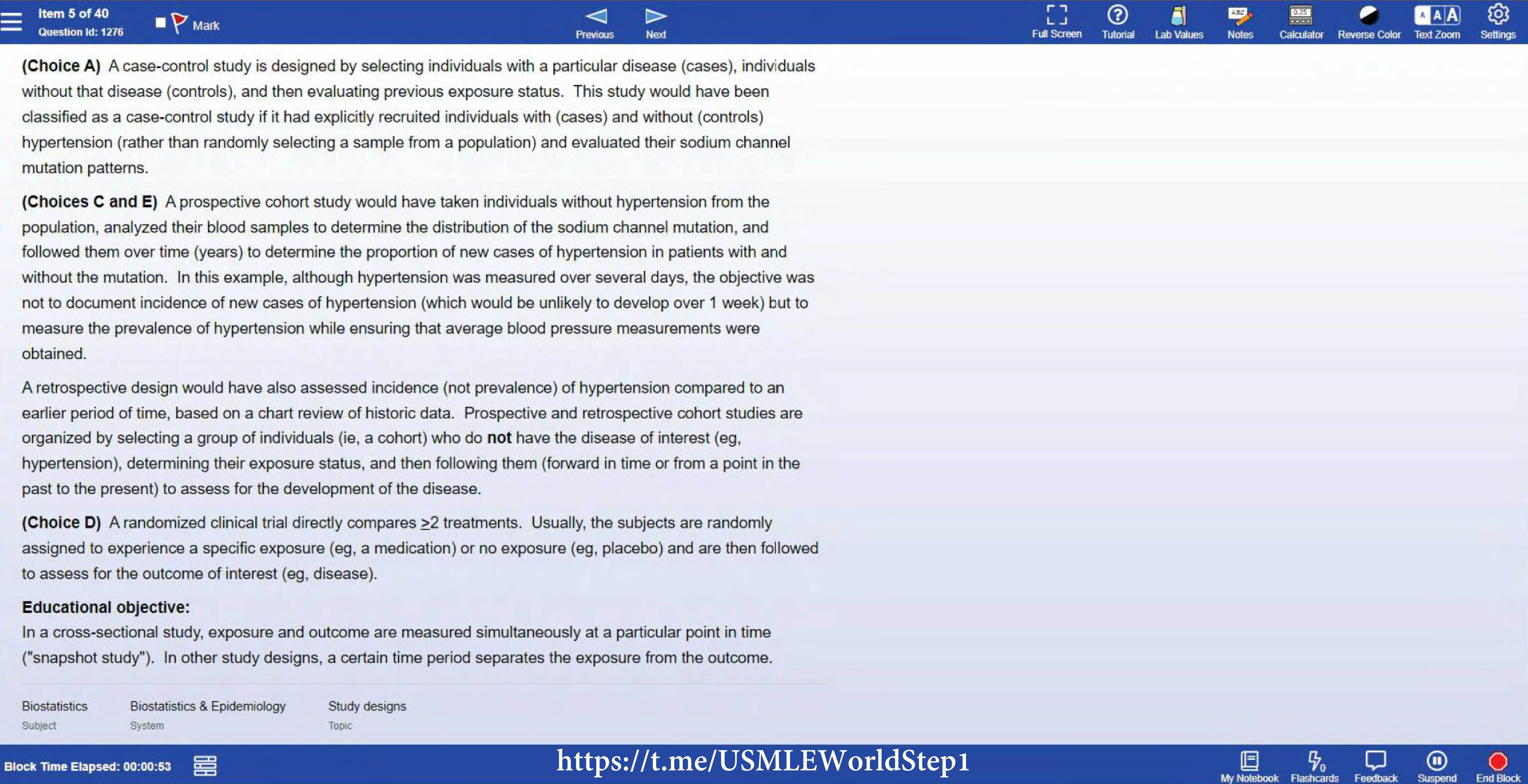


A **cross-sectional** study (also known as a prevalence study) simultaneously measures exposures and outcomes. The cross-sectional study has a **"snapshot"** design that is frequently used in surveys, mostly because it is inexpensive and easy to perform. In this example, a snapshot was obtained of individuals randomly selected from the population; their blood samples were analyzed for the presence of the sodium channel protein mutation and the prevalence of hypertension was calculated. The subjects' blood pressure was measured over 7 days to obtain an average measurement (likely to limit the results being impacted by white-coat hypertension and other transient causes of hypertension). The major limitation of a cross-sectional study design is that a temporal relationship between exposure and outcome is not always clear. However, in this case, demonstrating a temporal relationship was straightforward because the possession of a specific genotype clearly precedes hypertension.

(Choice A) A case-control study is designed by selecting individuals with a particular disease (cases), individuals without that disease (controls), and then evaluating previous exposure status. This study would have been classified as a case-control study if it had explicitly recruited individuals with (cases) and without (controls) hypertension (rather than randomly selecting a sample from a population) and evaluated their sodium channel mutation patterns.

(Choices C and E) A prospective cohort study would have taken individuals without hypertension from the population, analyzed their blood samples to determine the distribution of the sodium channel mutation, and followed them over time (years) to determine the proportion of new cases of hypertension in patients with and without the mutation. In this example, although hypertension was measured over several days, the objective was not to document incidence of new cases of hypertension (which would be unlikely to develop over 1 week) but to measure the prevalence of hypertension while ensuring that average blood pressure measurements were obtained.

A retrospective design would have also assessed incidence (not prevalence) of hypertension compared to an earlier period of time, based on a chart review of historic data. Prospective and retrospective cohort studies are organized by selecting a group of individuals (ie, a cohort) who do **not** have the disease of interest (eg, hypertension), determining their exposure status, and then following them (forward in time or from a point in the past to the present) to assess for the development of the disease.



(Choice A) A case-control study is designed by selecting individuals with a particular disease (cases), individuals without that disease (controls), and then evaluating previous exposure status. This study would have been classified as a case-control study if it had explicitly recruited individuals with (cases) and without (controls) hypertension (rather than randomly selecting a sample from a population) and evaluated their sodium channel mutation patterns.

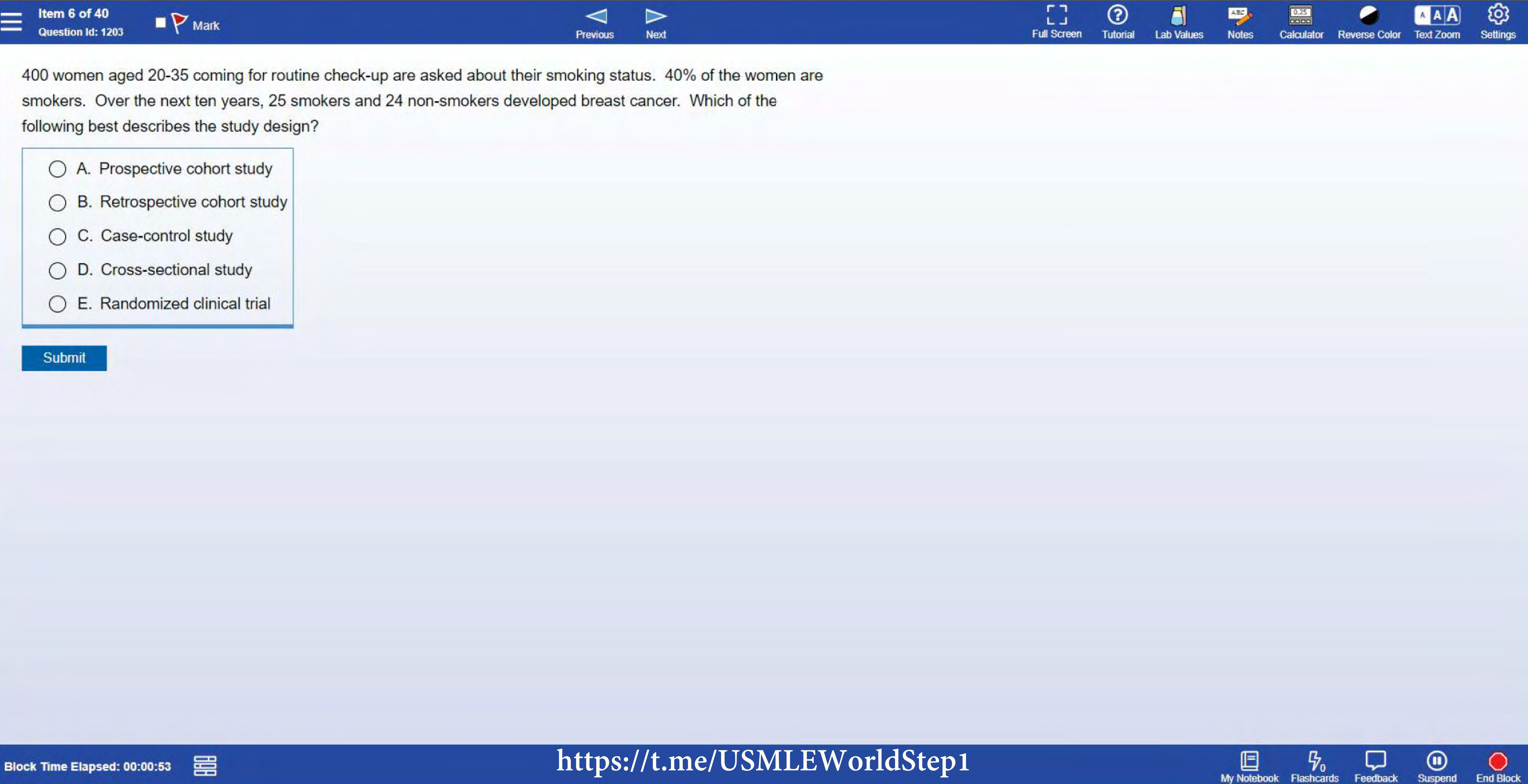
(Choices C and E) A prospective cohort study would have taken individuals without hypertension from the population, analyzed their blood samples to determine the distribution of the sodium channel mutation, and followed them over time (years) to determine the proportion of new cases of hypertension in patients with and without the mutation. In this example, although hypertension was measured over several days, the objective was not to document incidence of new cases of hypertension (which would be unlikely to develop over 1 week) but to measure the prevalence of hypertension while ensuring that average blood pressure measurements were obtained.

A retrospective design would have also assessed incidence (not prevalence) of hypertension compared to an earlier period of time, based on a chart review of historic data. Prospective and retrospective cohort studies are organized by selecting a group of individuals (ie, a cohort) who do **not** have the disease of interest (eg, hypertension), determining their exposure status, and then following them (forward in time or from a point in the past to the present) to assess for the development of the disease.

(Choice D) A randomized clinical trial directly compares ≥ 2 treatments. Usually, the subjects are randomly assigned to experience a specific exposure (eg, a medication) or no exposure (eg, placebo) and are then followed to assess for the outcome of interest (eg, disease).

Educational objective:
In a cross-sectional study, exposure and outcome are measured simultaneously at a particular point in time ("snapshot study"). In other study designs, a certain time period separates the exposure from the outcome.

Biostatistics	Biostatistics & Epidemiology	Study designs
Subject	System	Topic



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Question Id: 1203

400 women aged 20-35 coming for routine check-up are asked about their smoking status. 40% of the women are smokers. Over the next ten years, 25 smokers and 24 non-smokers developed breast cancer. Which of the following best describes the study design?

- ○ A. Prospective cohort study
- ○ B. Retrospective cohort study
- ○ C. Case-control study
- ○ D. Cross-sectional study
- ○ E. Randomized clinical trial

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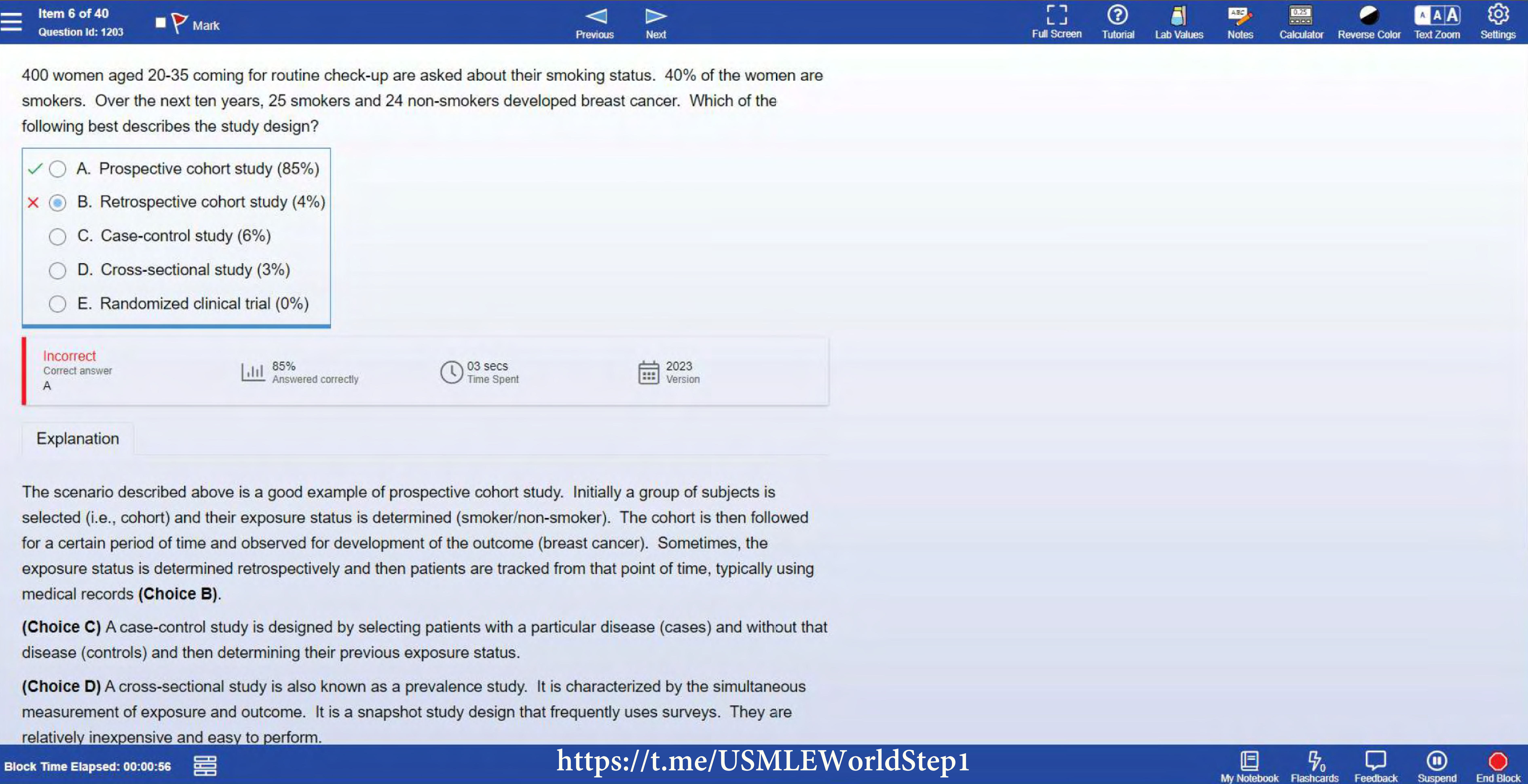
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✓ ○ A. Prospective cohort study (85%)
✗ ● B. Retrospective cohort study (4%)
○ C. Case-control study (6%)
○ D. Cross-sectional study (3%)
○ E. Randomized clinical trial (0%)

Incorrect
Correct answer
A

85%
Answered correctly

03 secs
Time Spent

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Explanation

The scenario described above is a good example of prospective cohort study. Initially a group of subjects is selected (i.e., cohort) and their exposure status is determined (smoker/non-smoker). The cohort is then followed for a certain period of time and observed for development of the outcome (breast cancer). Sometimes, the exposure status is determined retrospectively and then patients are tracked from that point of time, typically using medical records **(Choice B)**.

(Choice C) A case-control study is designed by selecting patients with a particular disease (cases) and without that disease (controls) and then determining their previous exposure status.

(Choice D) A cross-sectional study is also known as a prevalence study. It is characterized by the simultaneous measurement of exposure and outcome. It is a snapshot study design that frequently uses surveys. They are relatively inexpensive and easy to perform.

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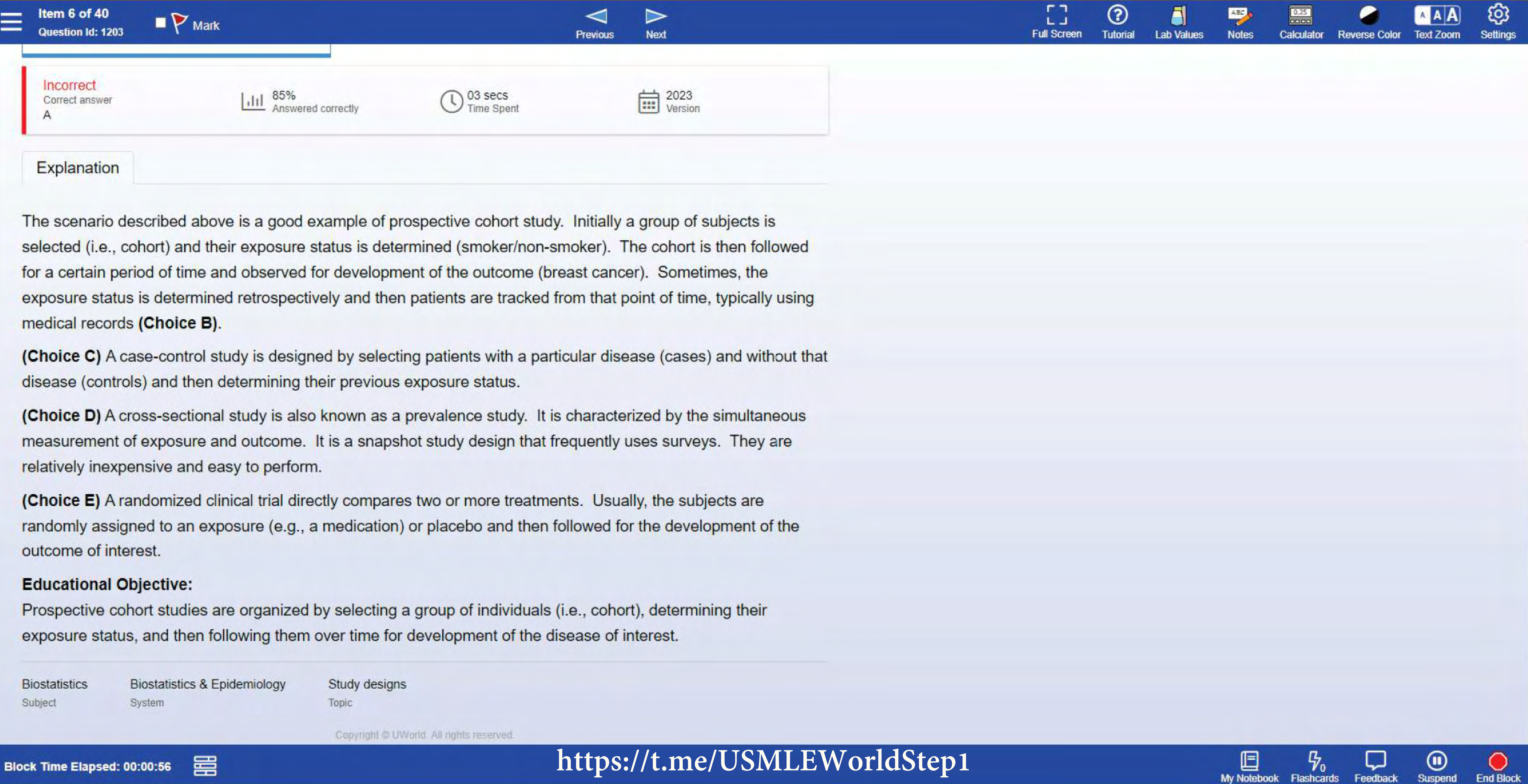
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Incorrect
Correct answer
A

85%
Answered correctly

03 secs
Time Spent

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Version

Explanation

The scenario described above is a good example of prospective cohort study. Initially a group of subjects is selected (i.e., cohort) and their exposure status is determined (smoker/non-smoker). The cohort is then followed for a certain period of time and observed for development of the outcome (breast cancer). Sometimes, the exposure status is determined retrospectively and then patients are tracked from that point of time, typically using medical records **(Choice B)**.

(Choice C) A case-control study is designed by selecting patients with a particular disease (cases) and without that disease (controls) and then determining their previous exposure status.

(Choice D) A cross-sectional study is also known as a prevalence study. It is characterized by the simultaneous measurement of exposure and outcome. It is a snapshot study design that frequently uses surveys. They are relatively inexpensive and easy to perform.

(Choice E) A randomized clinical trial directly compares two or more treatments. Usually, the subjects are randomly assigned to an exposure (e.g., a medication) or placebo and then followed for the development of the outcome of interest.

Educational Objective:
Prospective cohort studies are organized by selecting a group of individuals (i.e., cohort), determining their exposure status, and then following them over time for development of the disease of interest.

Biostatistics	Biostatistics & Epidemiology	Study designs
Subject	System	Topic

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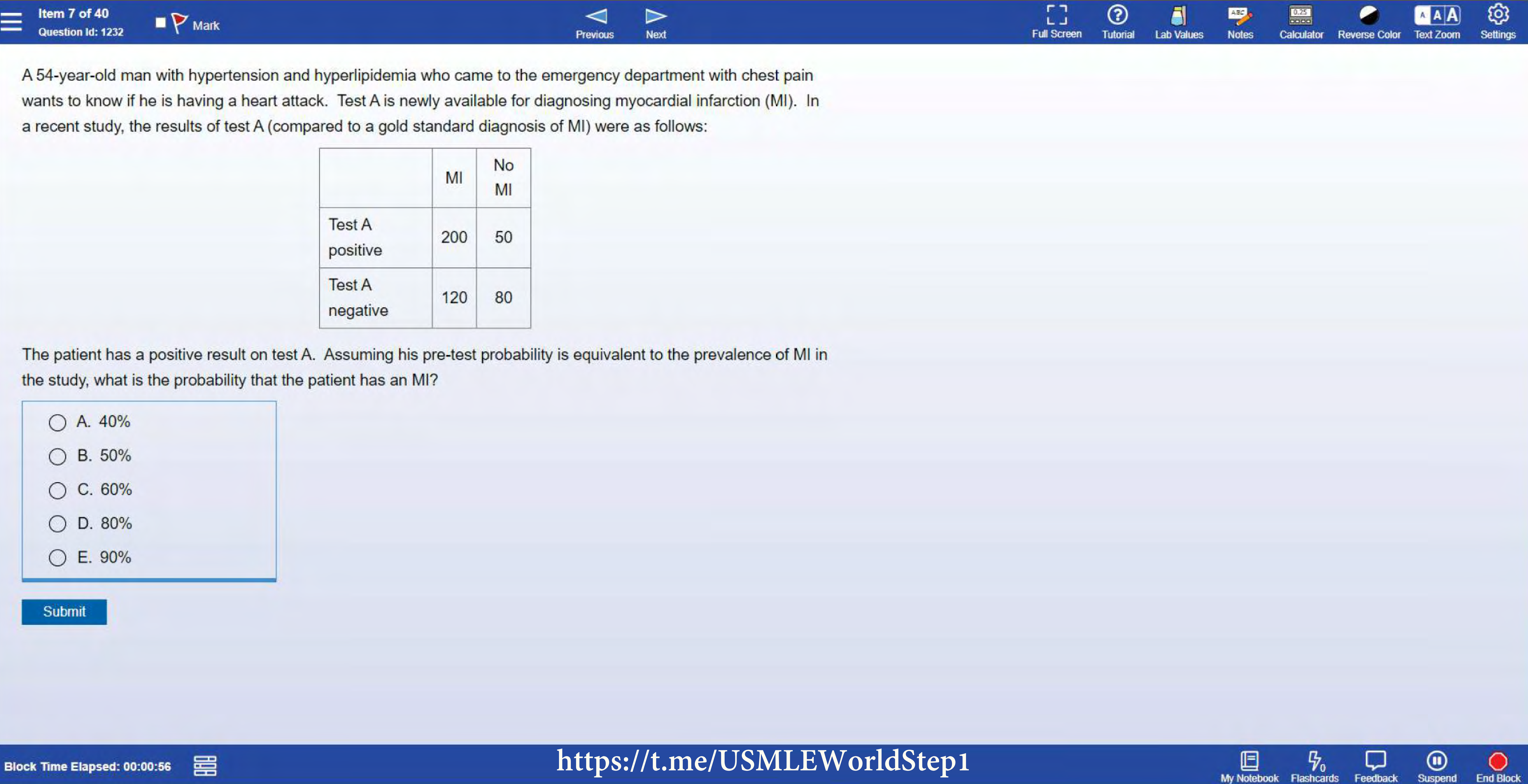
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A 54-year-old man with hypertension and hyperlipidemia who came to the emergency department with chest pain wants to know if he is having a heart attack. Test A is newly available for diagnosing myocardial infarction (MI). In a recent study, the results of test A (compared to a gold standard diagnosis of MI) were as follows:

	MI	No MI
Test A positive	200	50
Test A negative	120	80

The patient has a positive result on test A. Assuming his pre-test probability is equivalent to the prevalence of MI in the study, what is the probability that the patient has an MI?

○ A. 40%
○ B. 50%
○ C. 60%
○ D. 80%
○ E. 90%

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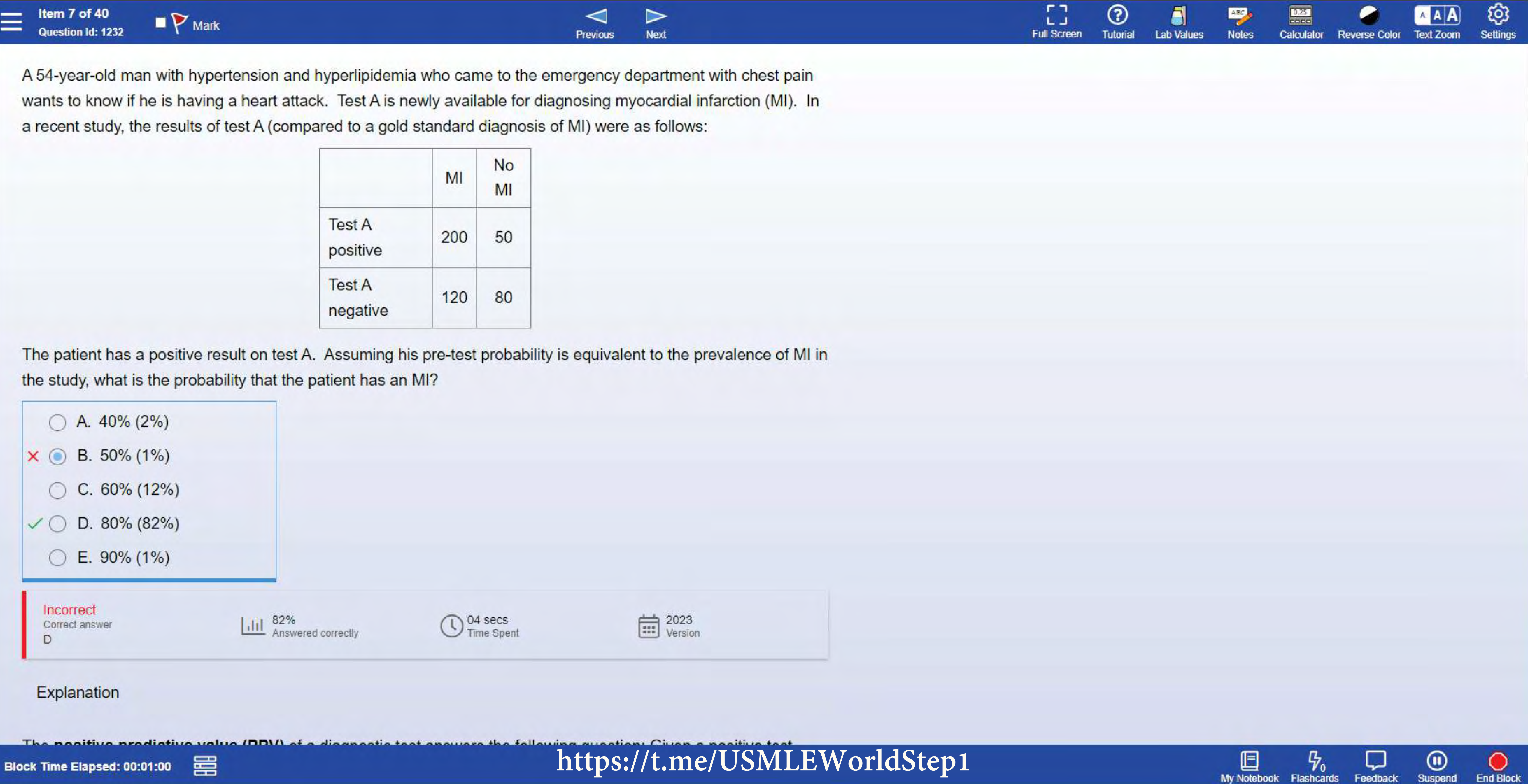
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	MI	No MI
Test A positive	200	50
Test A negative	120	80

The patient has a positive result on test A. Assuming his pre-test probability is equivalent to the prevalence of MI in the study, what is the probability that the patient has an MI?

- ○ A. 40% (2%)
- ✗ ● B. 50% (1%)
- ○ C. 60% (12%)
- ✓ ○ D. 80% (82%)
- ○ E. 90% (1%)

Incorrect
Correct answer
D

82%
Answered correctly

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Explanation

The positive predictive value (PPV) of a diagnostic test answers the following question: Given a positive test

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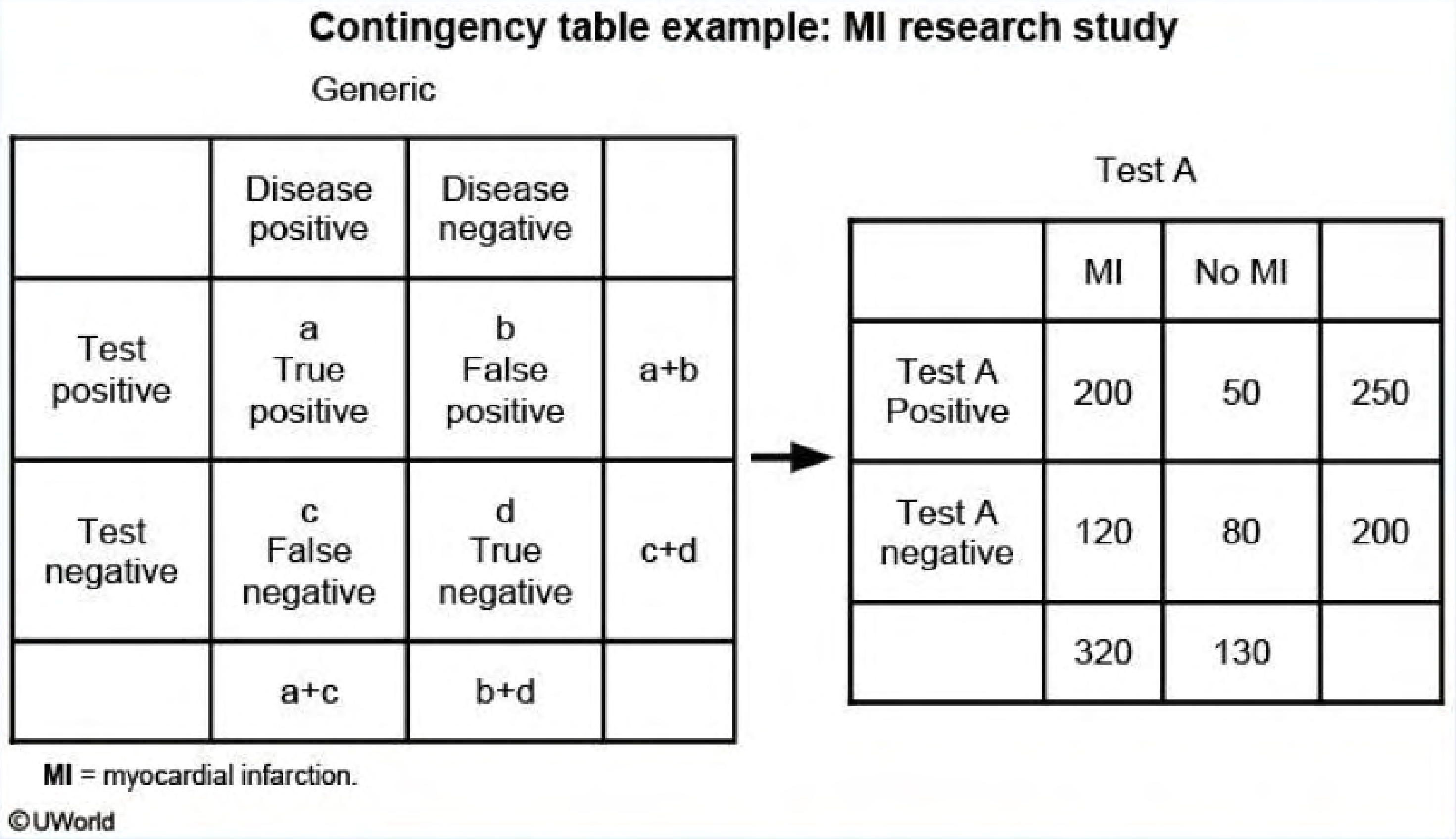
Explanation

The **positive predictive value (PPV)** of a diagnostic test answers the following question: Given a positive test result, what is the probability that a patient has the disease? PPV corresponds to the number of people with the disease who test positive among all those who test positive. Using a standard contingency (2 × 2) table, PPV = a / (a + b).



Contingency table example: MI research study

Generic

	Disease positive	Disease negative	
Test positive	a True positive	b False positive	a+b
Test negative	c False negative	d True negative	c+d
	a+c	b+d	

Test A

	MI	No MI	
Test A Positive	200	50	250
Test A negative	120	80	200
	320	130	

MI = myocardial infarction.

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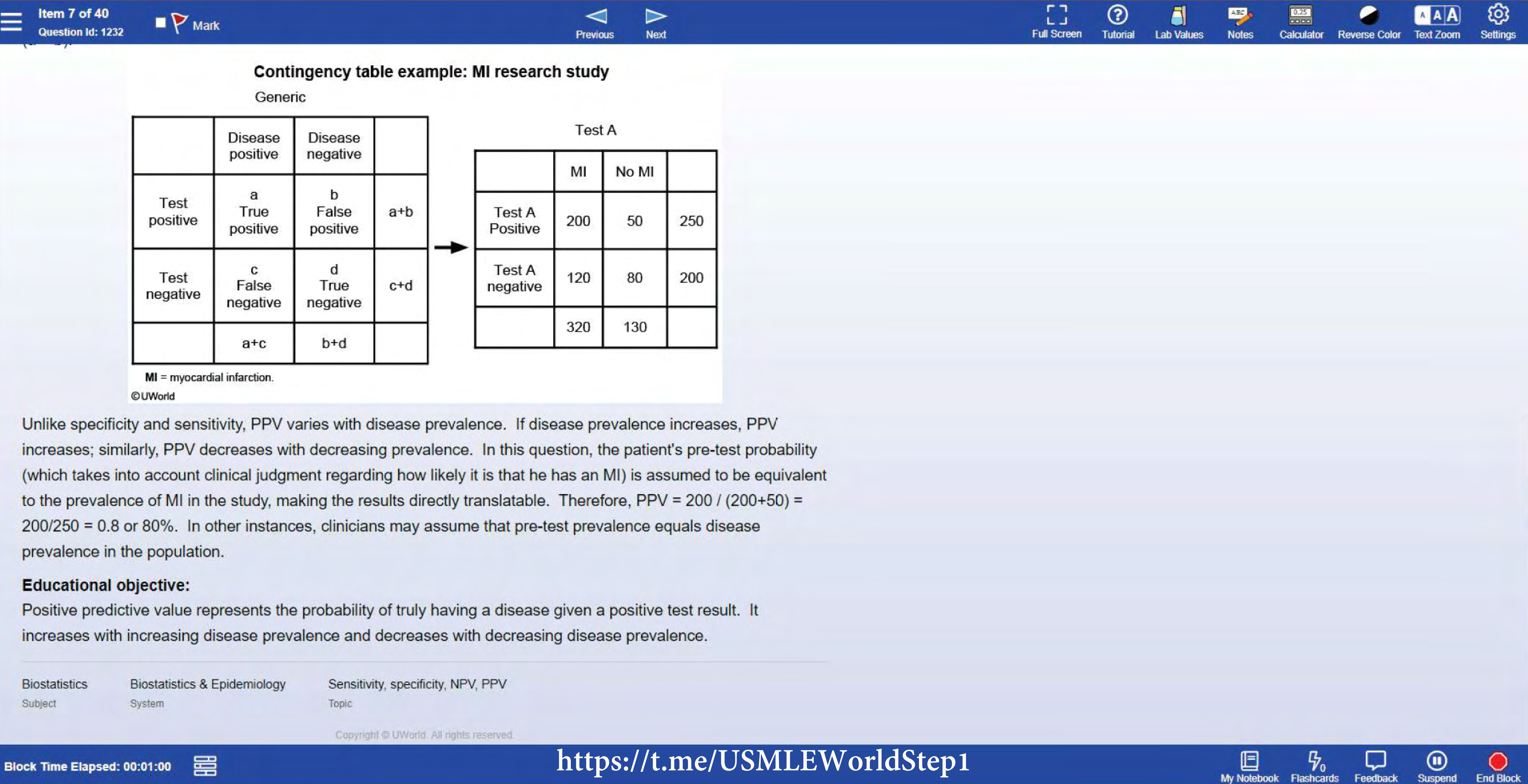
Unlike specificity and sensitivity, PPV varies with disease prevalence. If disease prevalence increases, PPV increases; similarly, PPV decreases with decreasing prevalence. In this question, the patient's pre-test probability (which takes into account clinical judgment regarding how likely it is that he has an MI) is assumed to be equivalent to the prevalence of MI in the study, making the results directly translatable. Therefore, PPV = 200 / (200+50) = 200/250 = 0.8 or 80%. In other instances, clinicians may assume that pre-test prevalence equals disease prevalence in the population.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Contingency table example: MI research study

Generic

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	a+c	b+d	

Test A

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Educational objective:

Positive predictive value represents the probability of truly having a disease given a positive test result. It increases with increasing disease prevalence and decreases with decreasing disease prevalence.

Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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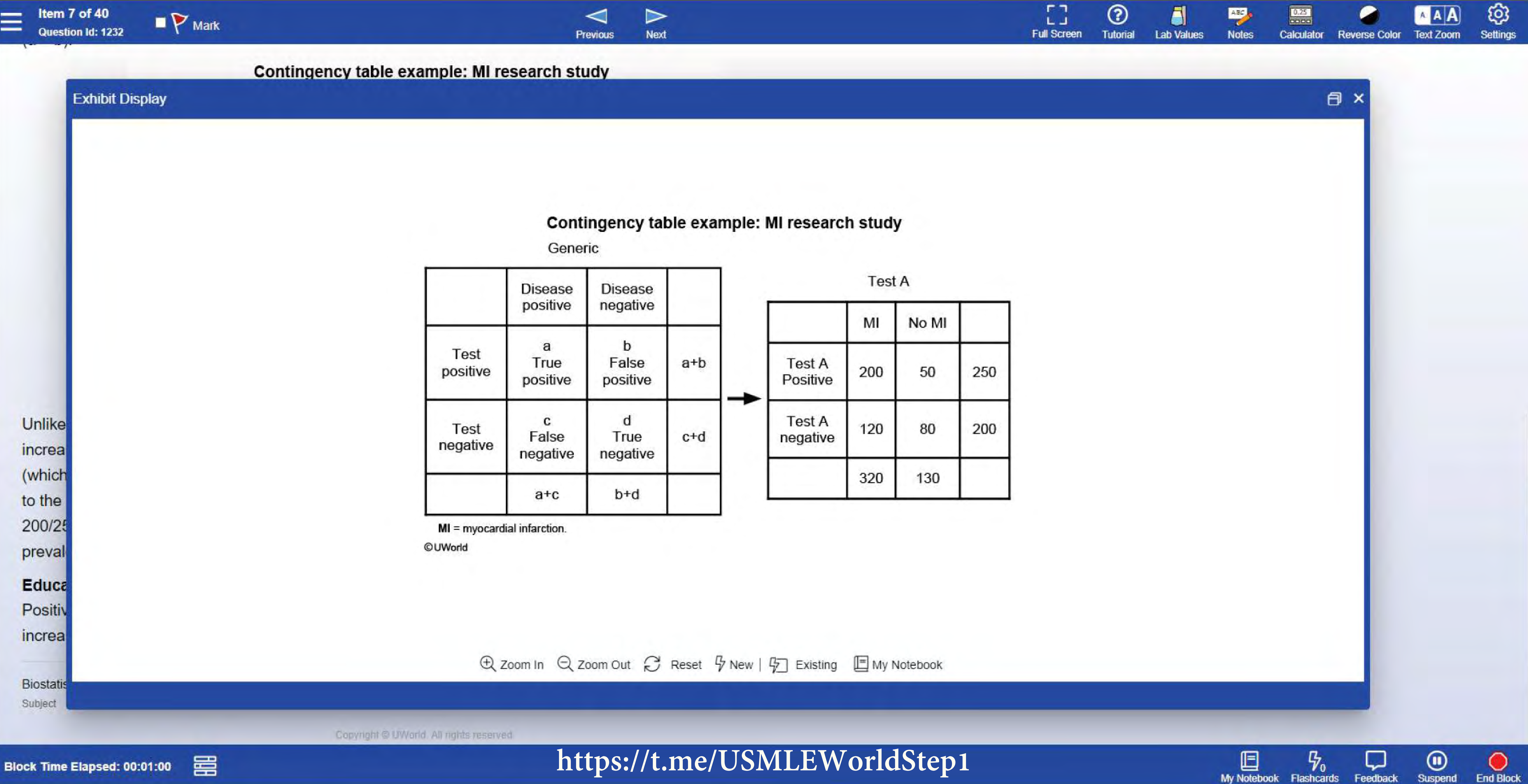
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Contingency table example: MI research study

Contingency table example: MI research study

Generic

	Disease positive	Disease negative	
Test positive	a True positive	b False positive	a+b
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	a+c	b+d	

Test A

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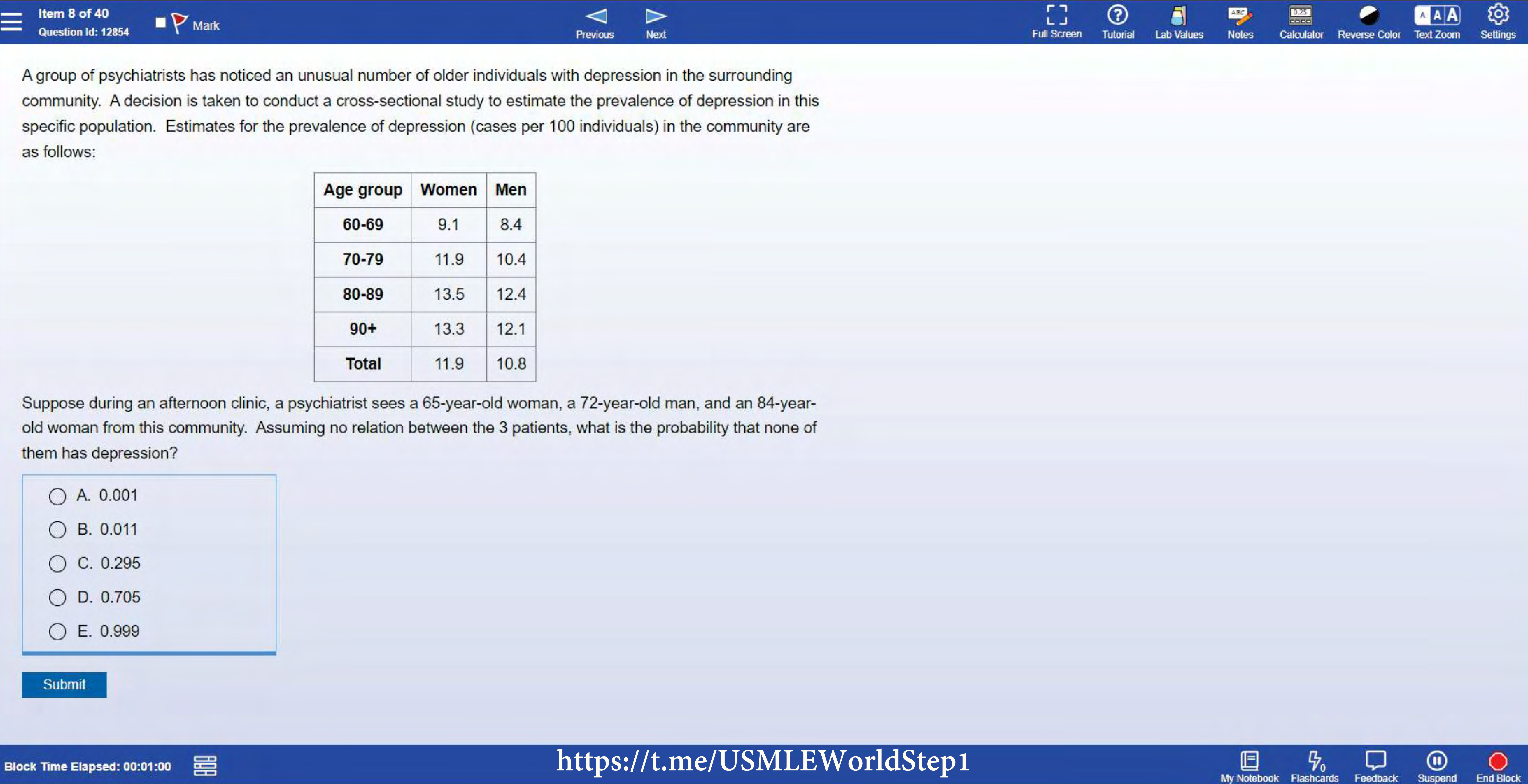
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A group of psychiatrists has noticed an unusual number of older individuals with depression in the surrounding community. A decision is taken to conduct a cross-sectional study to estimate the prevalence of depression in this specific population. Estimates for the prevalence of depression (cases per 100 individuals) in the community are as follows:

Age group	Women	Men
60-69	9.1	8.4
70-79	11.9	10.4
80-89	13.5	12.4
90+	13.3	12.1
Total	11.9	10.8

Suppose during an afternoon clinic, a psychiatrist sees a 65-year-old woman, a 72-year-old man, and an 84-year-old woman from this community. Assuming no relation between the 3 patients, what is the probability that none of them has depression?

○ A. 0.001
○ B. 0.011
○ C. 0.295
○ D. 0.705
○ E. 0.999

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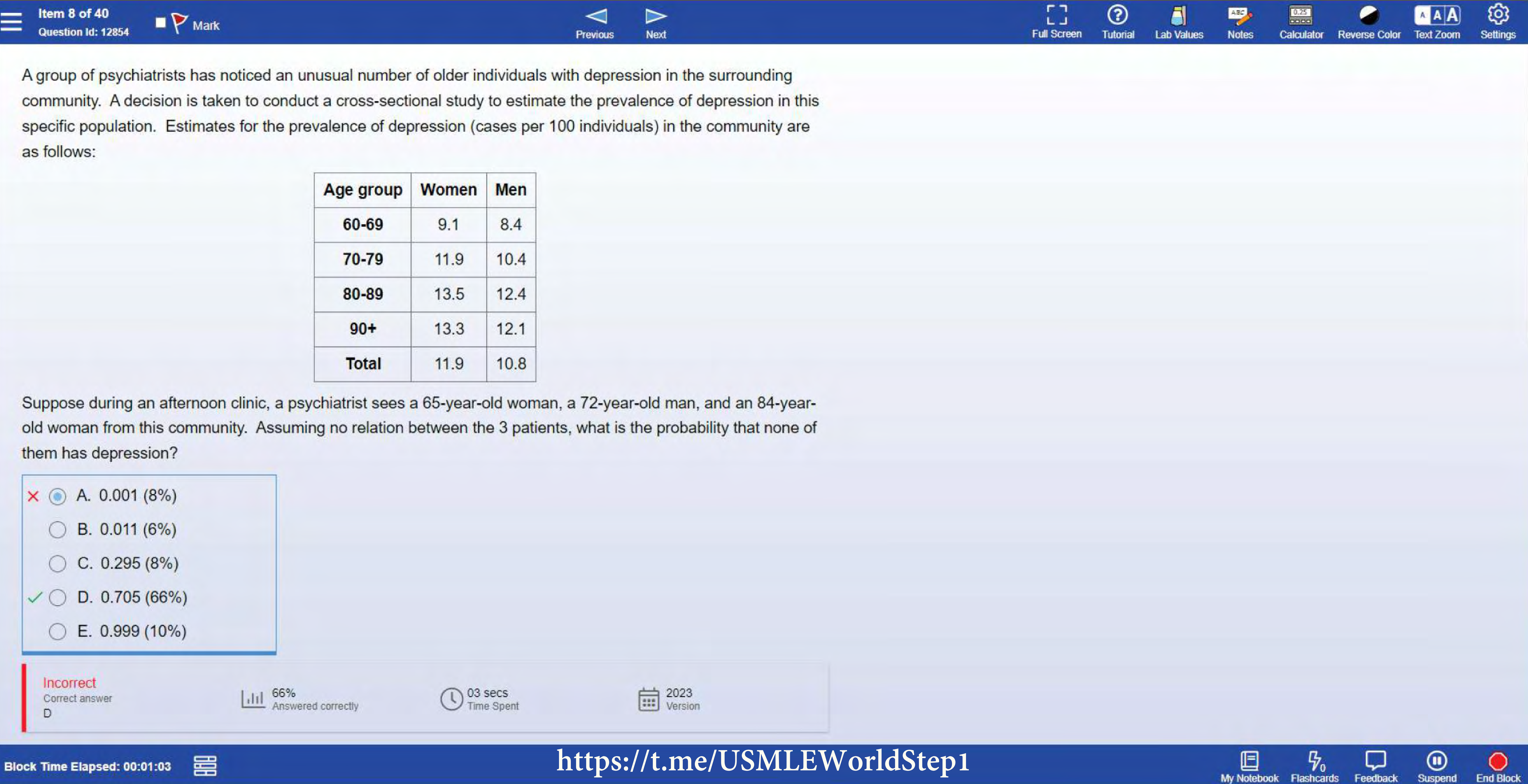
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Suppose during an afternoon clinic, a psychiatrist sees a 65-year-old woman, a 72-year-old man, and an 84-year-old woman from this community. Assuming no relation between the 3 patients, what is the probability that none of them has depression?

✗ ● A. 0.001 (8%)

○ B. 0.011 (6%)

○ C. 0.295 (8%)

✓ ○ D. 0.705 (66%)

○ E. 0.999 (10%)

Incorrect
Correct answer
D

66%
Answered correctly

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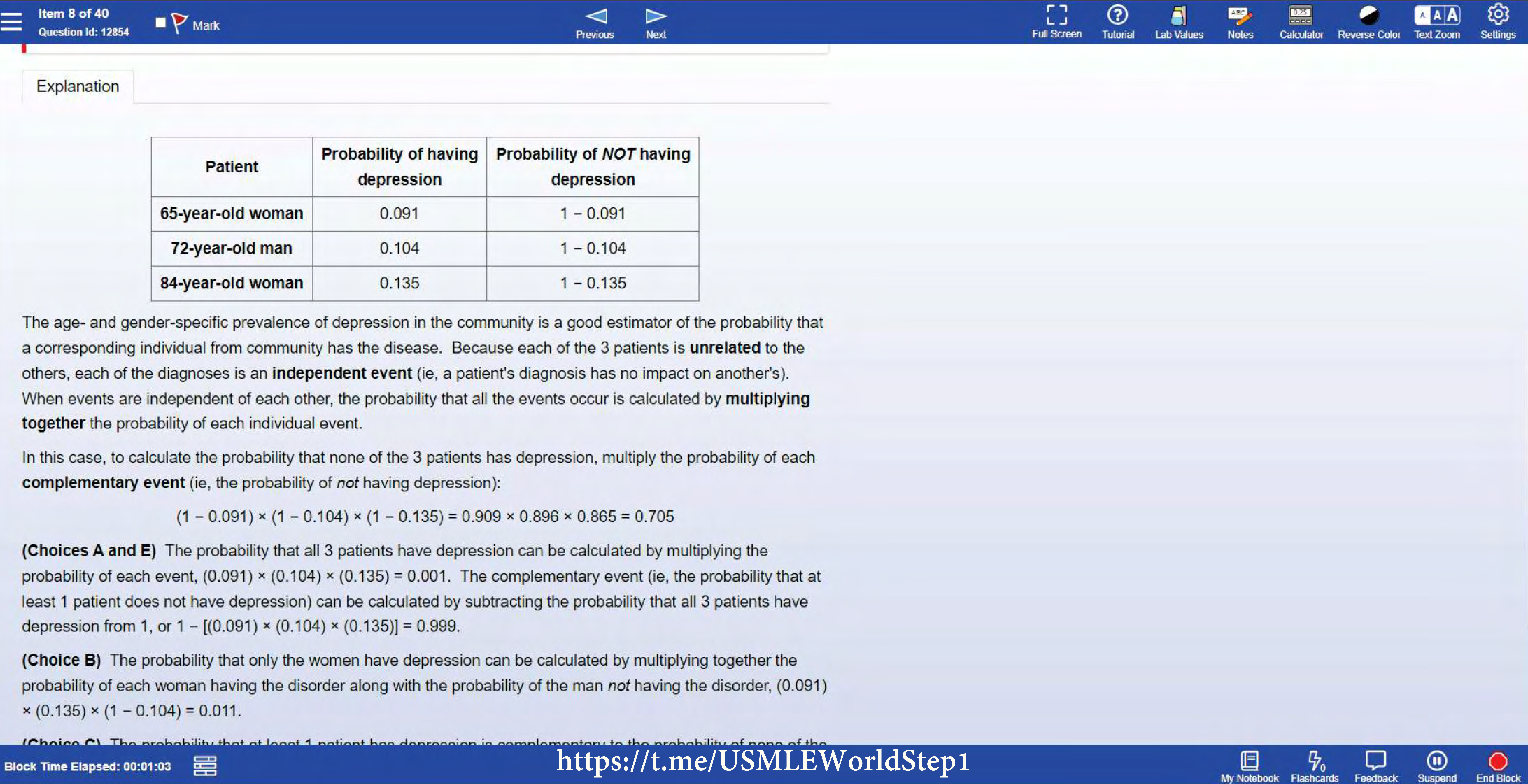
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Patient	Probability of having depression	Probability of *NOT* having depression
65-year-old woman	0.091	1 – 0.091
72-year-old man	0.104	1 – 0.104
84-year-old woman	0.135	1 – 0.135

The age- and gender-specific prevalence of depression in the community is a good estimator of the probability that a corresponding individual from community has the disease. Because each of the 3 patients is **unrelated** to the others, each of the diagnoses is an **independent event** (ie, a patient's diagnosis has no impact on another's). When events are independent of each other, the probability that all the events occur is calculated by **multiplying together** the probability of each individual event.

In this case, to calculate the probability that none of the 3 patients has depression, multiply the probability of each **complementary event** (ie, the probability of *not* having depression):

$$(1 - 0.091) \times (1 - 0.104) \times (1 - 0.135) = 0.909 \times 0.896 \times 0.865 = 0.705$$

(Choices A and E) The probability that all 3 patients have depression can be calculated by multiplying the probability of each event, (0.091) × (0.104) × (0.135) = 0.001. The complementary event (ie, the probability that at least 1 patient does not have depression) can be calculated by subtracting the probability that all 3 patients have depression from 1, or 1 – [(0.091) × (0.104) × (0.135)] = 0.999.

(Choice B) The probability that only the women have depression can be calculated by multiplying together the probability of each woman having the disorder along with the probability of the man *not* having the disorder, (0.091) × (0.135) × (1 – 0.104) = 0.011.

(Choice C) The probability that at least 1 patient has depression is complementary to the probability of none of the

The age- and gender-specific prevalence of depression in the community is a good estimator of the probability that a corresponding individual from community has the disease. Because each of the 3 patients is **unrelated** to the others, each of the diagnoses is an **independent event** (ie, a patient's diagnosis has no impact on another's). When events are independent of each other, the probability that all the events occur is calculated by **multiplying together** the probability of each individual event.

In this case, to calculate the probability that none of the 3 patients has depression, multiply the probability of each **complementary event** (ie, the probability of *not* having depression):

$$(1 - 0.091) \times (1 - 0.104) \times (1 - 0.135) = 0.909 \times 0.896 \times 0.865 = 0.705$$

(Choices A and E) The probability that all 3 patients have depression can be calculated by multiplying the probability of each event, (0.091) × (0.104) × (0.135) = 0.001. The complementary event (ie, the probability that at least 1 patient does not have depression) can be calculated by subtracting the probability that all 3 patients have depression from 1, or 1 − [(0.091) × (0.104) × (0.135)] = 0.999.

(Choice B) The probability that only the women have depression can be calculated by multiplying together the probability of each woman having the disorder along with the probability of the man *not* having the disorder, (0.091) × (0.135) × (1 − 0.104) = 0.011.

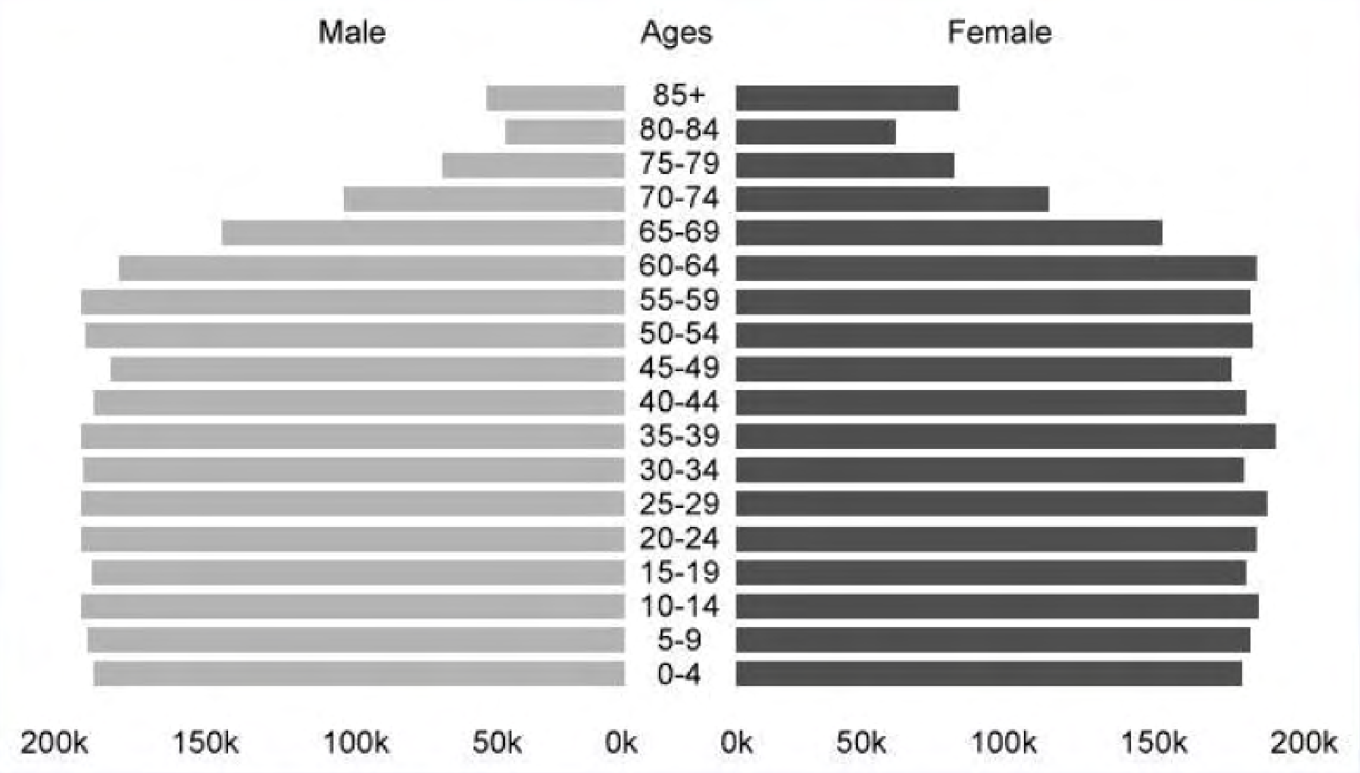
(Choice C) The probability that at least 1 patient has depression is complementary to the probability of none of the 3 patients having depression. It can be calculated by subtracting the probability that none of the 3 patients has depression from 1, or 1 − [(1 − 0.091) × (1 − 0.104) × (1 − 0.135)] = 0.295.

Educational objective:

The multiplication law of probability states that the probability of 2 or more independent events occurring together can be calculated by multiplying the individual probabilities of each event. The multiplication law of probability can be extended to complementary events (1 − probability of event) in the same manner.

Biostatistics	Biostatistics & Epidemiology	Probability theory
Subject	System	Topic

The population pyramid of all races and ethnicities for a certain state in the United States is shown below.



Which of the following statements best describes the population of this specific state?

○ A. Life expectancy is low due to its high mortality rate

○ B. The high birth rate indicates the population is growing

○ C. The population is shrinking due to the migration of older people

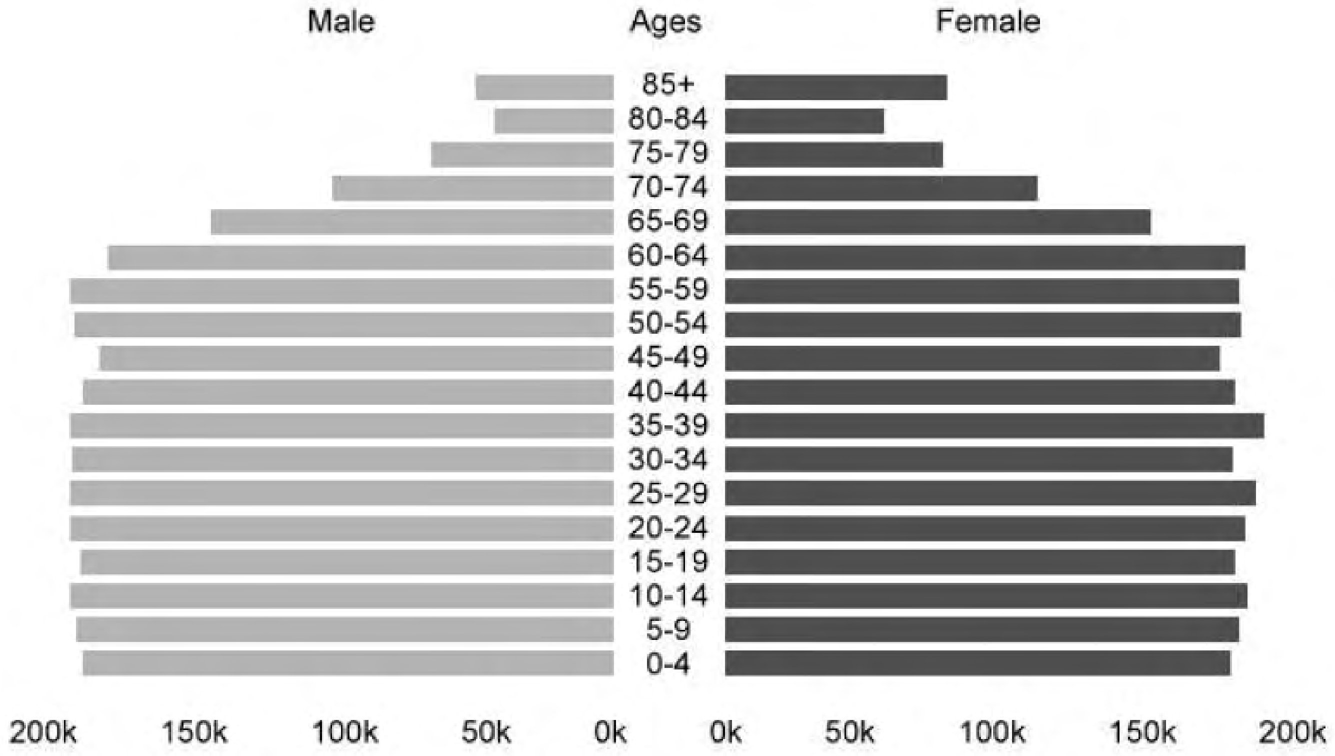
○ D. The similar number of people in each age cohort indicates the population is stable

○ E. The state has a young population because of its high birth rate

Submit

The population pyramid of all races and ethnicities for a certain state in the United States is shown below

Exhibit Display



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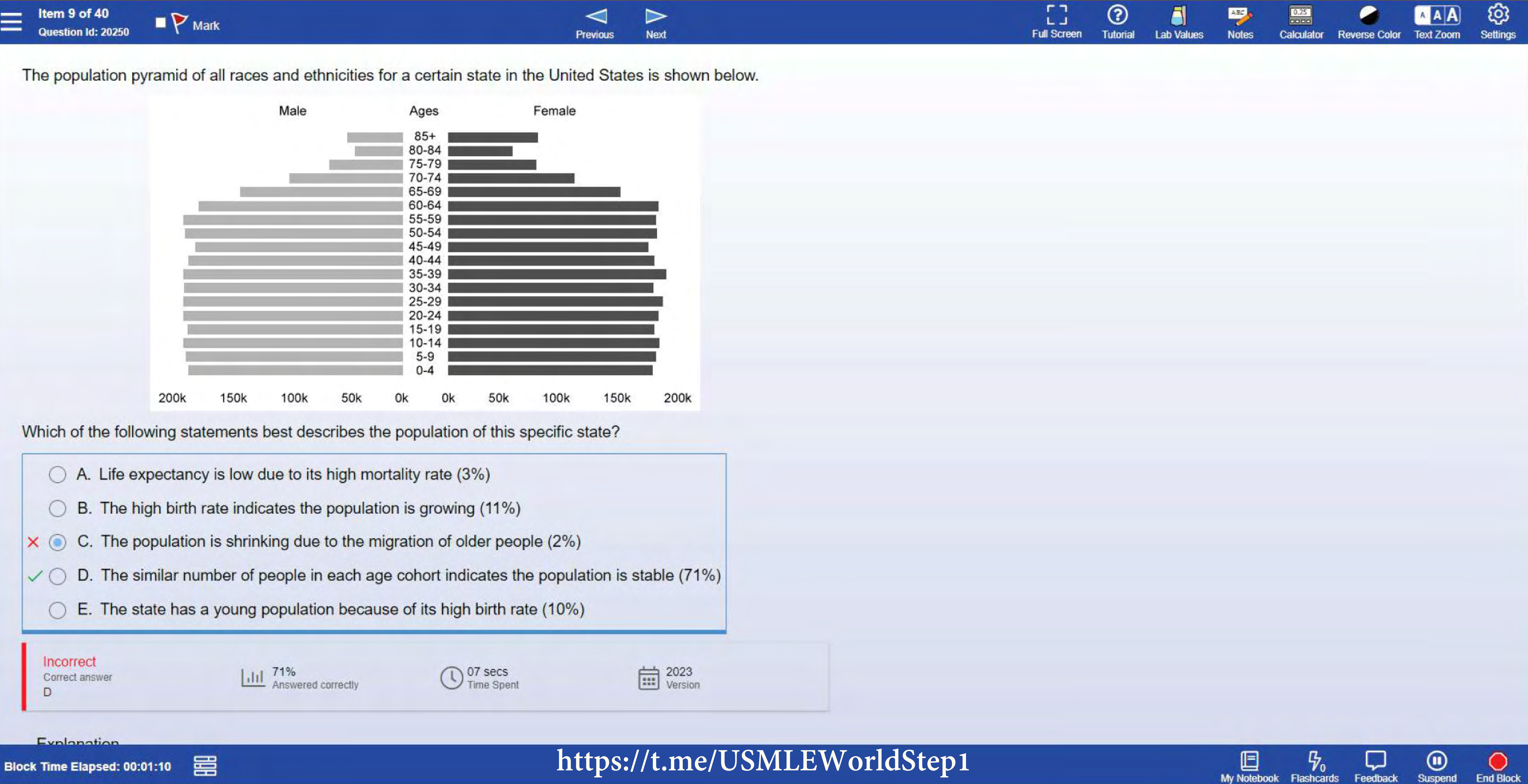
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The population pyramid of all races and ethnicities for a certain state in the United States is shown below.

Male
Ages
Female
85+
80-84
75-79
70-74
65-69
60-64
55-59
50-54
45-49
40-44
35-39
30-34
25-29
20-24
15-19
10-14
5-9
0-4
200k
150k
100k
50k
0k
0k
50k
100k
150k
200k

Which of the following statements best describes the population of this specific state?

○ A. Life expectancy is low due to its high mortality rate (3%)

○ B. The high birth rate indicates the population is growing (11%)

✗ ● C. The population is shrinking due to the migration of older people (2%)

✓ ○ D. The similar number of people in each age cohort indicates the population is stable (71%)

○ E. The state has a young population because of its high birth rate (10%)

Incorrect
Correct answer
D

71%
Answered correctly

07 secs
Time Spent

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Explanation

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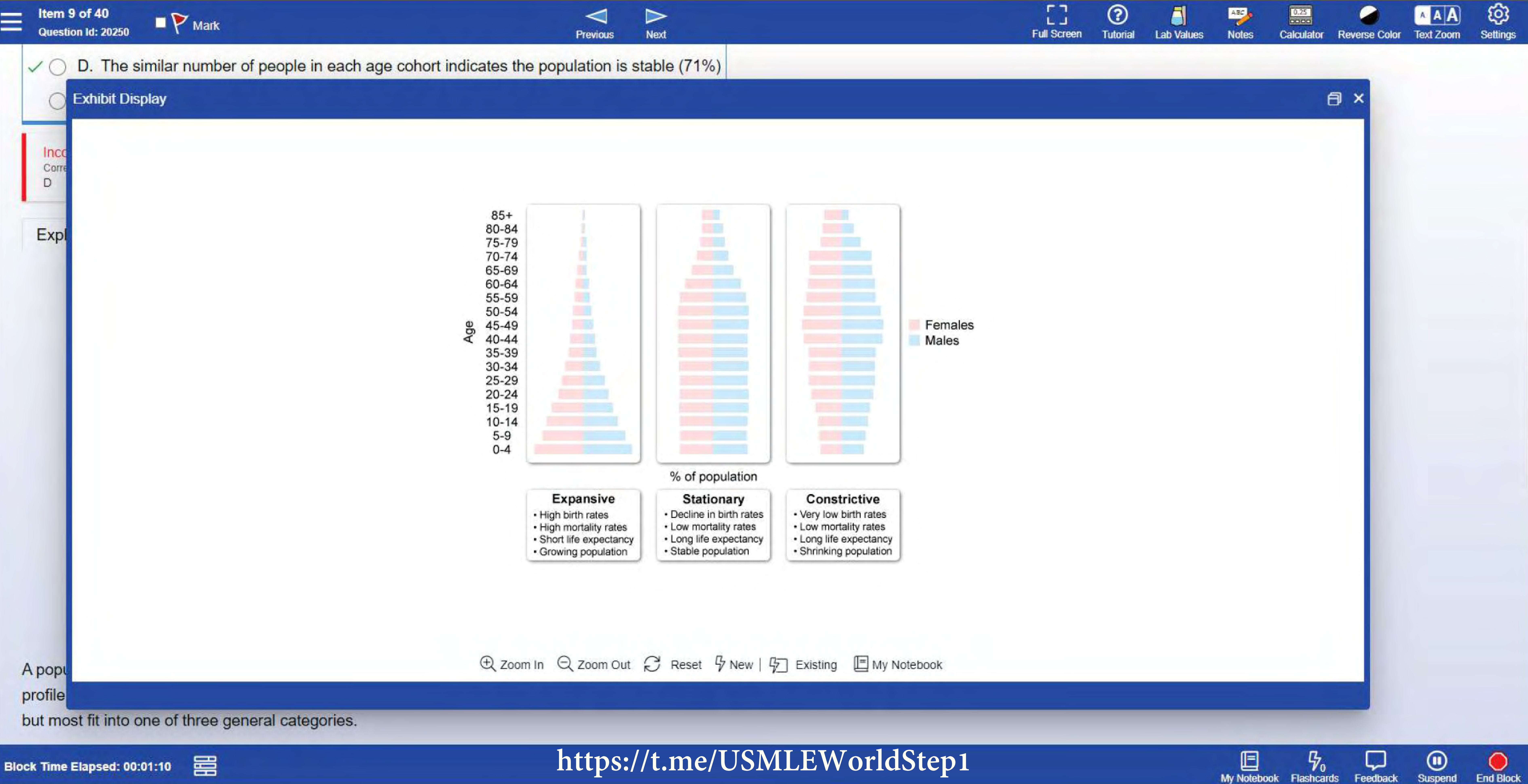
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85+
80-84
75-79
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65-69
60-64
55-59
50-54
45-49
40-44
35-39
30-34
25-29
20-24
15-19
10-14
5-9
0-4
% of population
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Males
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✓ ○ D. The similar number of people in each age cohort indicates the population is stable (71%)

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Expl

Expansive
- High birth rates
- High mortality rates
- Short life expectancy
- Growing population

Stationary
- Decline in birth rates
- Low mortality rates
- Long life expectancy
- Stable population

Constrictive
- Very low birth rates
- Low mortality rates
- Long life expectancy
- Shrinking population

A popu
profile
but most fit into one of three general categories.

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A population pyramid displays the percentage of individuals in each age cohort to describe the current population profile, and to project how the population will increase/decrease in the future. Every population pyramid is unique, but most fit into one of three general categories.

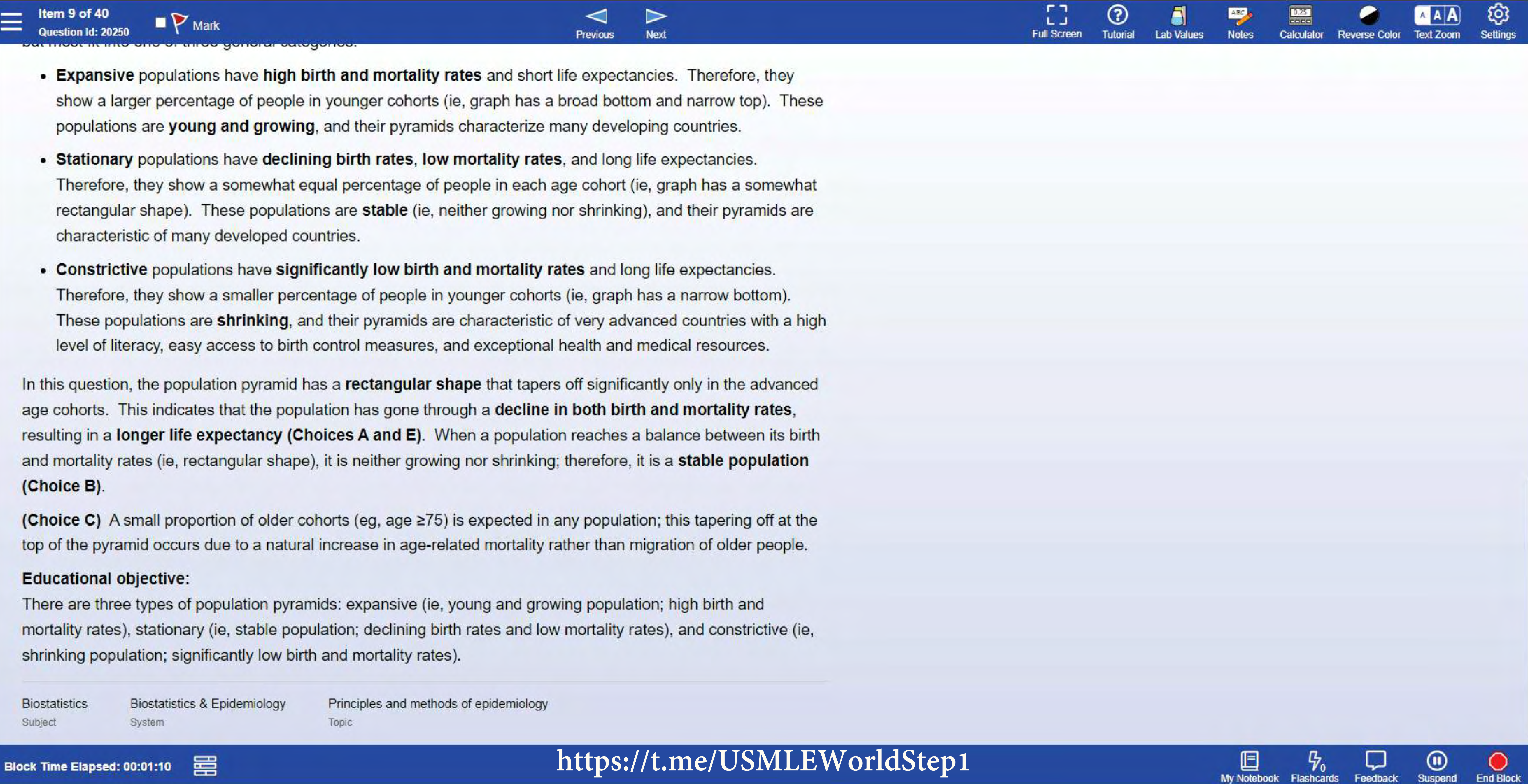
- **Expansive** populations have **high birth and mortality rates** and short life expectancies. Therefore, they show a larger percentage of people in younger cohorts (ie, graph has a broad bottom and narrow top). These populations are **young and growing**, and their pyramids characterize many developing countries.
- **Stationary** populations have **declining birth rates**, **low mortality rates**, and long life expectancies. Therefore, they show a somewhat equal percentage of people in each age cohort (ie, graph has a somewhat rectangular shape). These populations are **stable** (ie, neither growing nor shrinking), and their pyramids are characteristic of many developed countries.
- **Constrictive** populations have **significantly low birth and mortality rates** and long life expectancies. Therefore, they show a smaller percentage of people in younger cohorts (ie, graph has a narrow bottom). These populations are **shrinking**, and their pyramids are characteristic of very advanced countries with a high level of literacy, easy access to birth control measures, and exceptional health and medical resources.

In this question, the population pyramid has a **rectangular shape** that tapers off significantly only in the advanced age cohorts. This indicates that the population has gone through a **decline in both birth and mortality rates**, resulting in a **longer life expectancy (Choices A and E)**. When a population reaches a balance between its birth and mortality rates (ie, rectangular shape), it is neither growing nor shrinking; therefore, it is a **stable population (Choice B)**.

(Choice C) A small proportion of older cohorts (eg, age ≥75) is expected in any population; this tapering off at the top of the pyramid occurs due to a natural increase in age-related mortality rather than migration of older people.

Educational objective:

There are three types of population pyramids: expansive (ie, young and growing population; high birth and mortality rates), stationary (ie, stable population; declining birth rates and low mortality rates), and constrictive (ie, shrinking population; significantly low birth and mortality rates).



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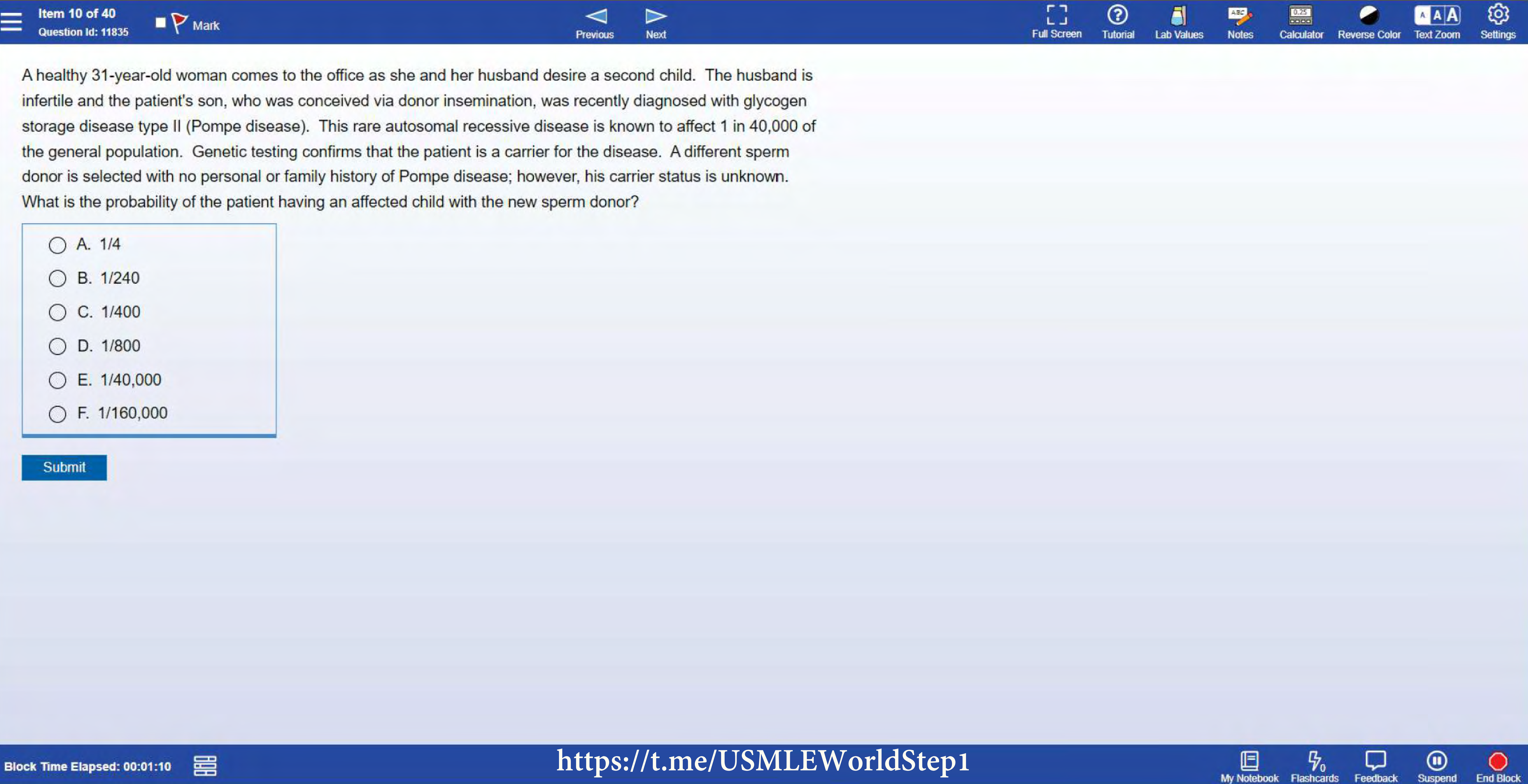
There are three types of population pyramids: expansive (ie, young and growing population; high birth and mortality rates), stationary (ie, stable population; declining birth rates and low mortality rates), and constrictive (ie, shrinking population; significantly low birth and mortality rates).

Biostatistics	Biostatistics & Epidemiology	Principles and methods of epidemiology
Subject	System	Topic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A healthy 31-year-old woman comes to the office as she and her husband desire a second child. The husband is infertile and the patient's son, who was conceived via donor insemination, was recently diagnosed with glycogen storage disease type II (Pompe disease). This rare autosomal recessive disease is known to affect 1 in 40,000 of the general population. Genetic testing confirms that the patient is a carrier for the disease. A different sperm donor is selected with no personal or family history of Pompe disease; however, his carrier status is unknown. What is the probability of the patient having an affected child with the new sperm donor?

○ A. 1/4
○ B. 1/240
○ C. 1/400
○ D. 1/800
○ E. 1/40,000
○ F. 1/160,000

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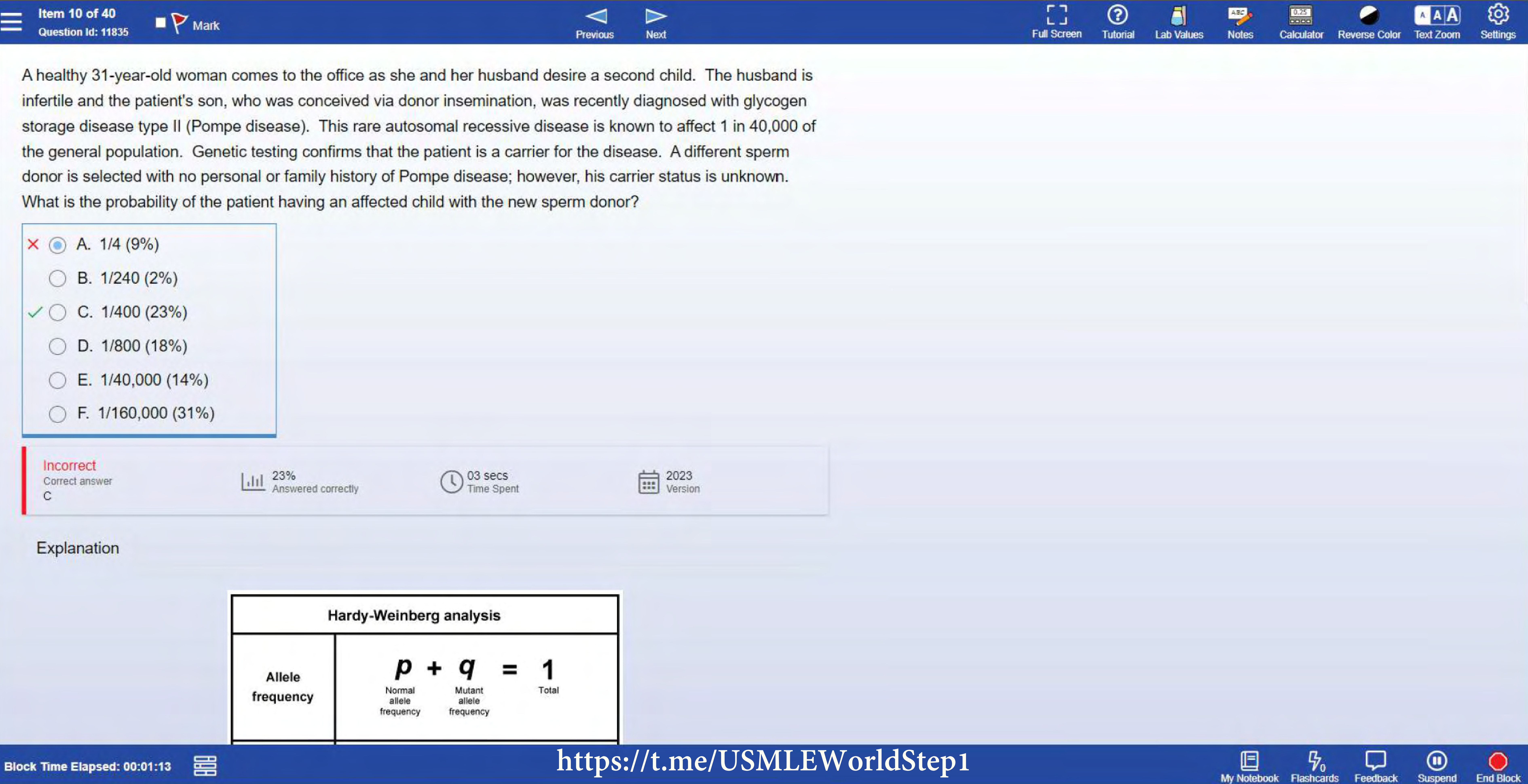
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- ✗ ● A. 1/4 (9%)
- ○ B. 1/240 (2%)
- ✓ ○ C. 1/400 (23%)
- ○ D. 1/800 (18%)
- ○ E. 1/40,000 (14%)
- ○ F. 1/160,000 (31%)

Incorrect
Correct answer
C

23%
Answered correctly

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Explanation

Hardy-Weinberg analysis	
Allele frequency	$p + q = 1$ p: Normal allele frequency q: Mutant allele frequency 1: Total

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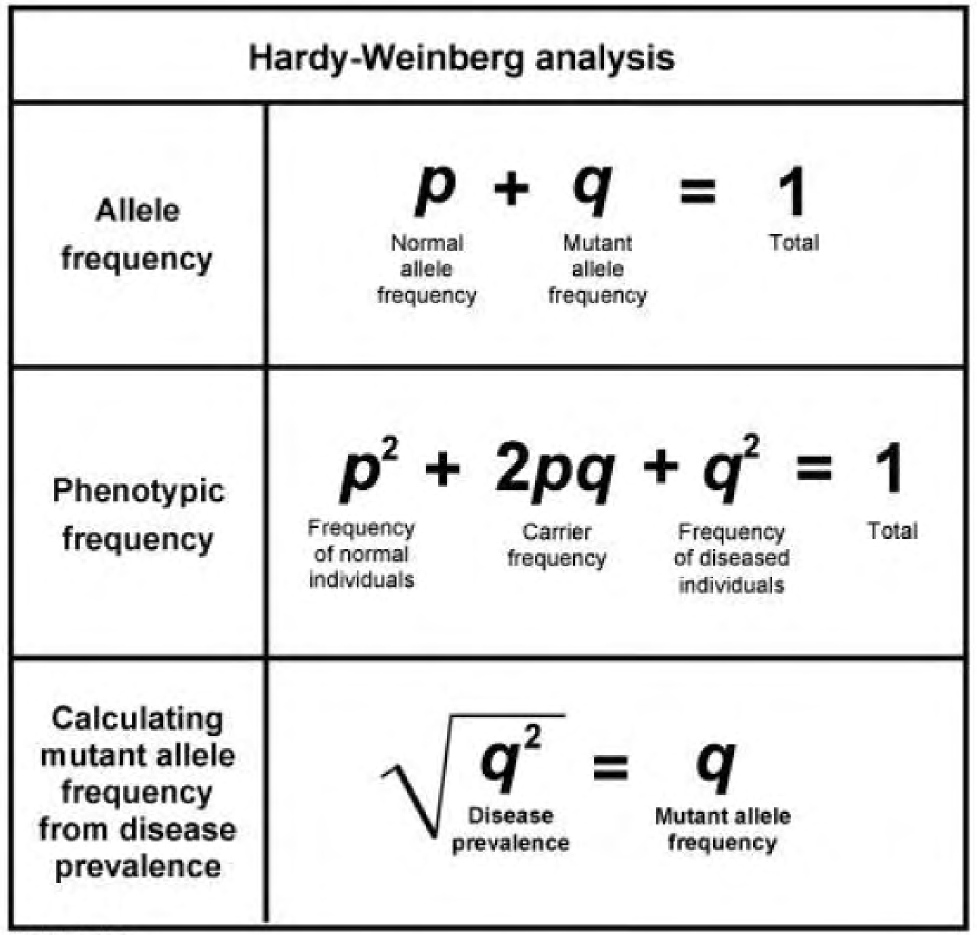

Hardy-Weinberg analysis	
Allele frequency	$p + q = 1$ Normal allele frequency; Mutant allele frequency; Total
Phenotypic frequency	$p^2 + 2pq + q^2 = 1$ Frequency of normal individuals; Carrier frequency; Frequency of diseased individuals; Total
Calculating mutant allele frequency from disease prevalence	$\sqrt{q^2} = q$ Disease prevalence; Mutant allele frequency

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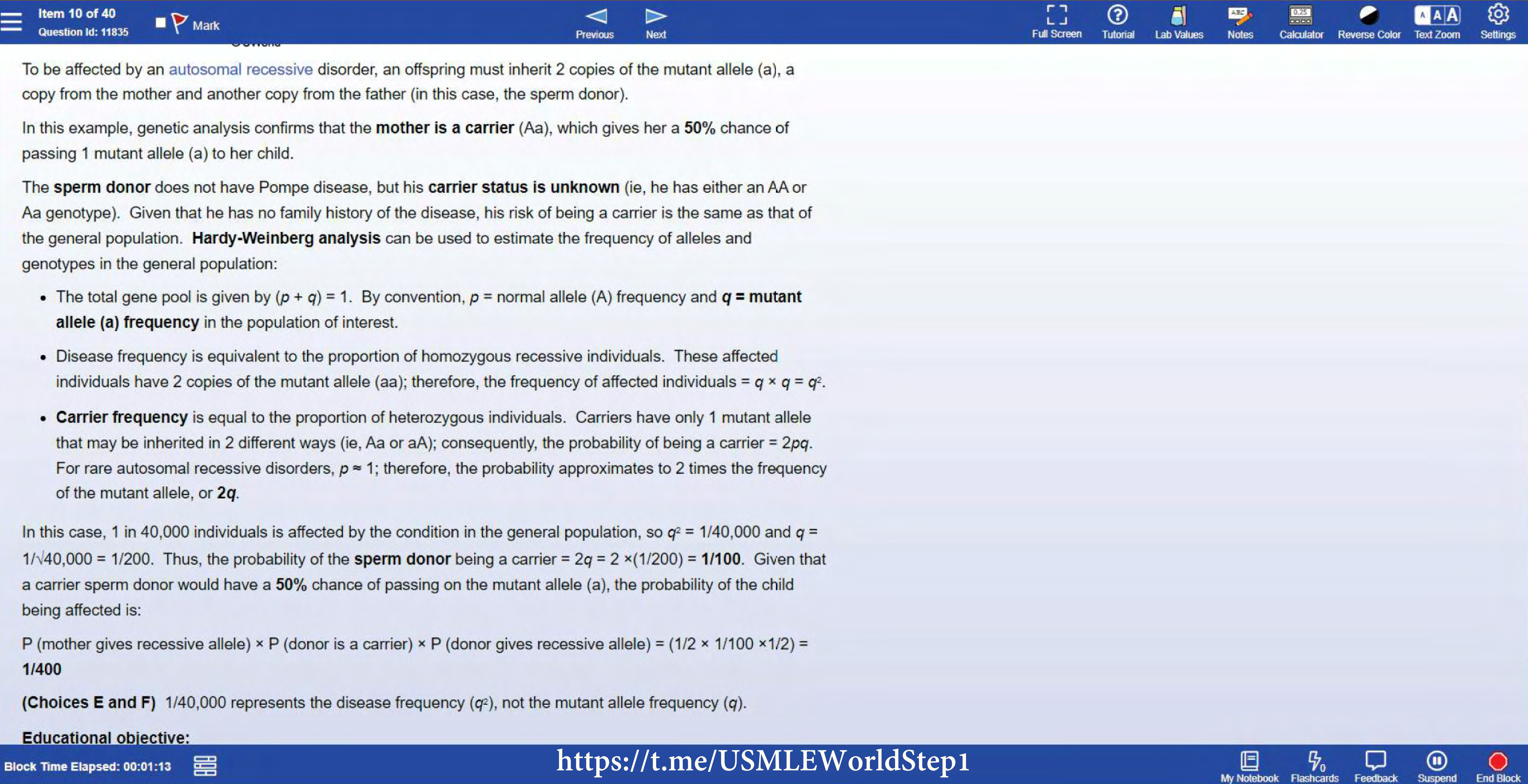
- The total gene pool is given by (p + q) = 1. By convention, p = normal allele (A) frequency and **q = mutant**



To be affected by an autosomal recessive disorder, an offspring must inherit 2 copies of the mutant allele (a), a copy from the mother and another copy from the father (in this case, the sperm donor).

In this example, genetic analysis confirms that the **mother is a carrier** (Aa), which gives her a **50%** chance of passing 1 mutant allele (a) to her child.

The **sperm donor** does not have Pompe disease, but his **carrier status is unknown** (ie, he has either an AA or Aa genotype). Given that he has no family history of the disease, his risk of being a carrier is the same as that of the general population. **Hardy-Weinberg analysis** can be used to estimate the frequency of alleles and genotypes in the general population:

- The total gene pool is given by $(p + q) = 1$. By convention, p = normal allele (A) frequency and **q = mutant allele (a) frequency** in the population of interest.
- Disease frequency is equivalent to the proportion of homozygous recessive individuals. These affected individuals have 2 copies of the mutant allele (aa); therefore, the frequency of affected individuals = $q \times q = q^2$.
- **Carrier frequency** is equal to the proportion of heterozygous individuals. Carriers have only 1 mutant allele that may be inherited in 2 different ways (ie, Aa or aA); consequently, the probability of being a carrier = $2pq$. For rare autosomal recessive disorders, $p \approx 1$; therefore, the probability approximates to 2 times the frequency of the mutant allele, or **$2q$**.

In this case, 1 in 40,000 individuals is affected by the condition in the general population, so $q^2 = 1/40{,}000$ and $q = 1/\sqrt{40{,}000} = 1/200$. Thus, the probability of the **sperm donor** being a carrier = $2q = 2 \times (1/200) =$ **1/100**. Given that a carrier sperm donor would have a **50%** chance of passing on the mutant allele (a), the probability of the child being affected is:

P (mother gives recessive allele) × P (donor is a carrier) × P (donor gives recessive allele) = (1/2 × 1/100 ×1/2) = **1/400**

(Choices E and F) 1/40,000 represents the disease frequency (q^2), not the mutant allele frequency (q).

Educational objective:

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Aa genotype). Given that he has no family history of the disease, his risk of being a carrier is the same as that of the general population. **Hardy-Weinberg analysis** can be used to estimate the frequency of alleles and genotypes in the general population:

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P (mother gives recessive allele) × P (donor is a carrier) × P (donor gives recessive allele) = (1/2 × 1/100 ×1/2) = **1/400**

(Choices E and F) 1/40,000 represents the disease frequency (q^2), not the mutant allele frequency (q).

Educational objective:
The Hardy-Weinberg equation can be used to estimate carrier frequency, disease frequency, and frequency of different genotypes if at least 1 of these values is known.

References

- A century of Hardy-Weinberg equilibrium.
- Prevalence estimation for monogenic autosomal recessive diseases using population-based genetic data.

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mutant allele frequency from disease

$\sqrt{q^2} = q$

Disease Mutant allele

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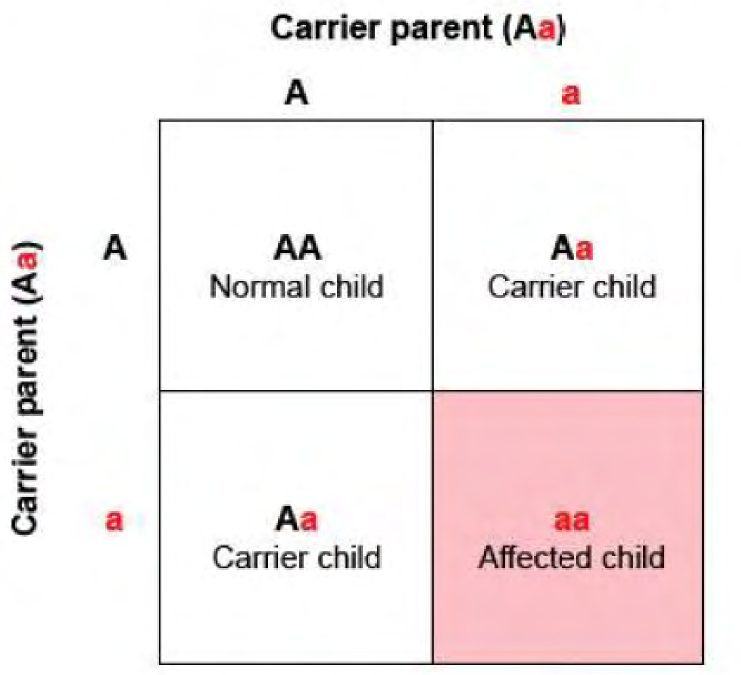
Autosomal recessive inheritance


Carrier parent (Aa)
A
a
Carrier parent (Aa)
A
a
AA
Normal child
Aa
Carrier child
Aa
Carrier child
aa
Affected child

Offspring have 25% chance of being affected

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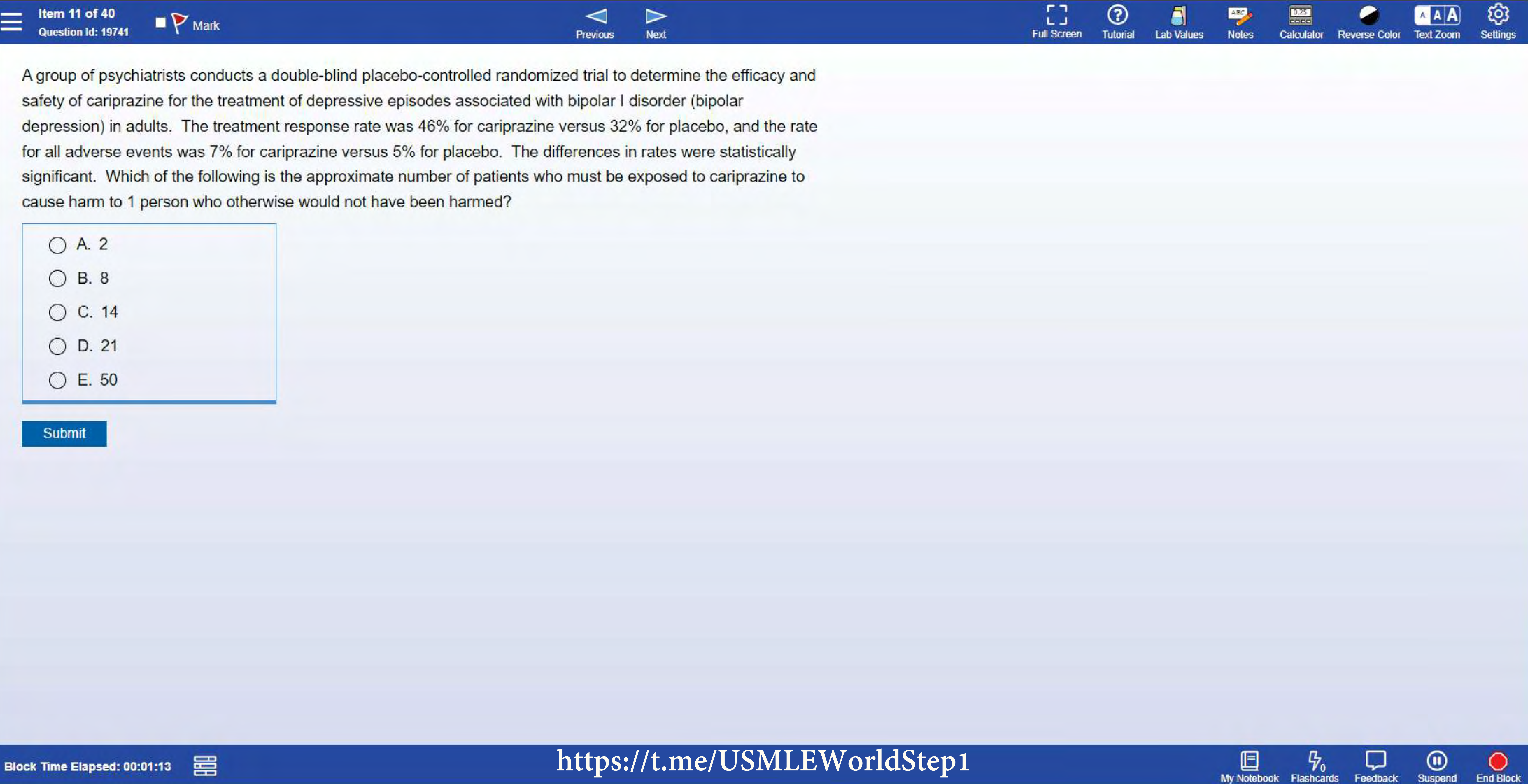
P (mother gives recessive allele) × P (donor is a carrier) × P (donor gives recessive allele) = (1/2 × 1/100 ×1/2) =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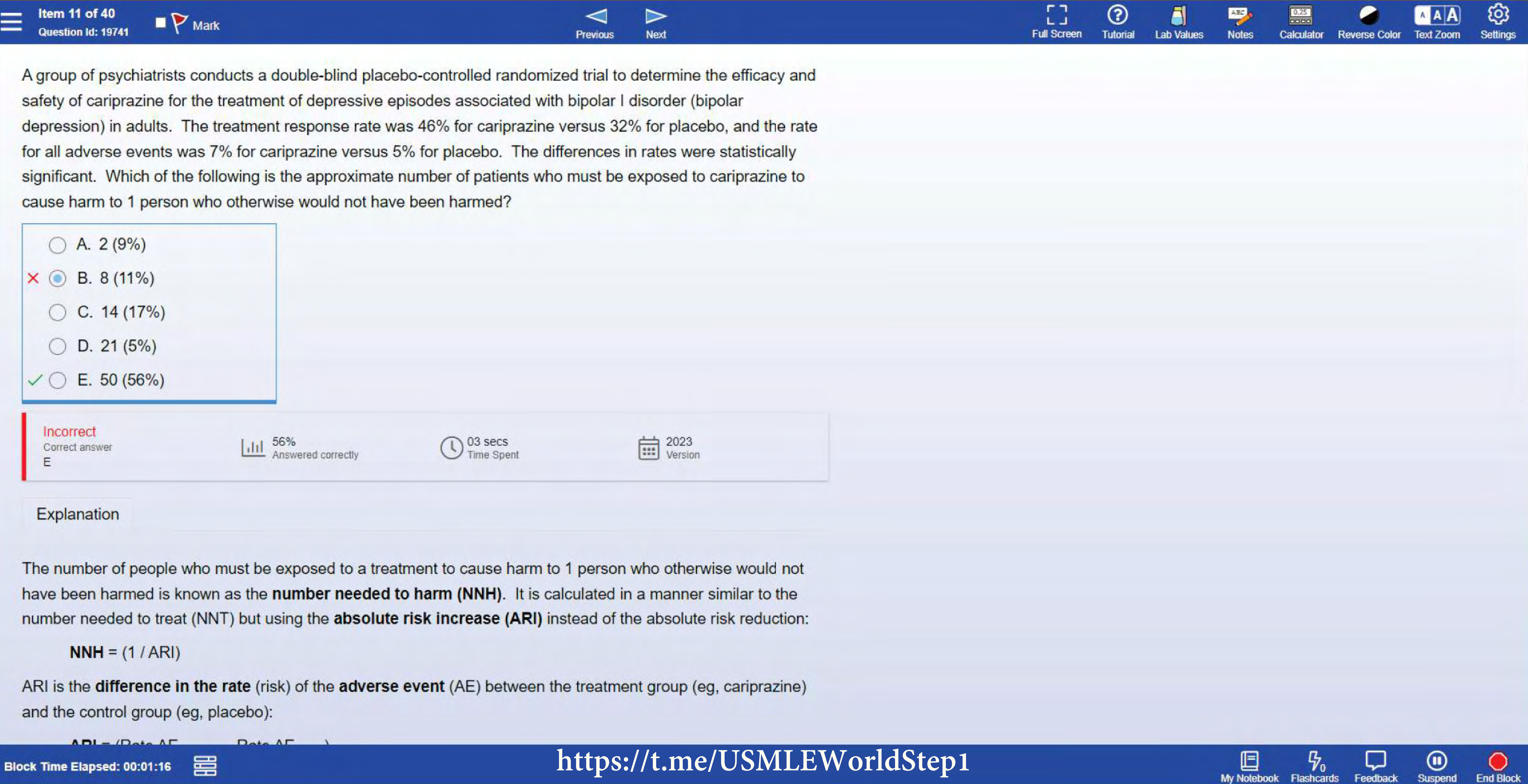
A group of psychiatrists conducts a double-blind placebo-controlled randomized trial to determine the efficacy and safety of cariprazine for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults. The treatment response rate was 46% for cariprazine versus 32% for placebo, and the rate for all adverse events was 7% for cariprazine versus 5% for placebo. The differences in rates were statistically significant. Which of the following is the approximate number of patients who must be exposed to cariprazine to cause harm to 1 person who otherwise would not have been harmed?

○ A. 2
○ B. 8
○ C. 14
○ D. 21
○ E. 50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○ A. 2 (9%)
✗ ● B. 8 (11%)
○ C. 14 (17%)
○ D. 21 (5%)
✓ ○ E. 50 (56%)

Incorrect
Correct answer
E

56%
Answered correctly

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Explanation

The number of people who must be exposed to a treatment to cause harm to 1 person who otherwise would not have been harmed is known as the **number needed to harm (NNH)**. It is calculated in a manner similar to the number needed to treat (NNT) but using the **absolute risk increase (ARI)** instead of the absolute risk reduction:

NNH = (1 / ARI)

ARI is the **difference in the rate** (risk) of the **adverse event** (AE) between the treatment group (eg, cariprazine) and the control group (eg, placebo):

ARI = (Rate AE Rate AE)

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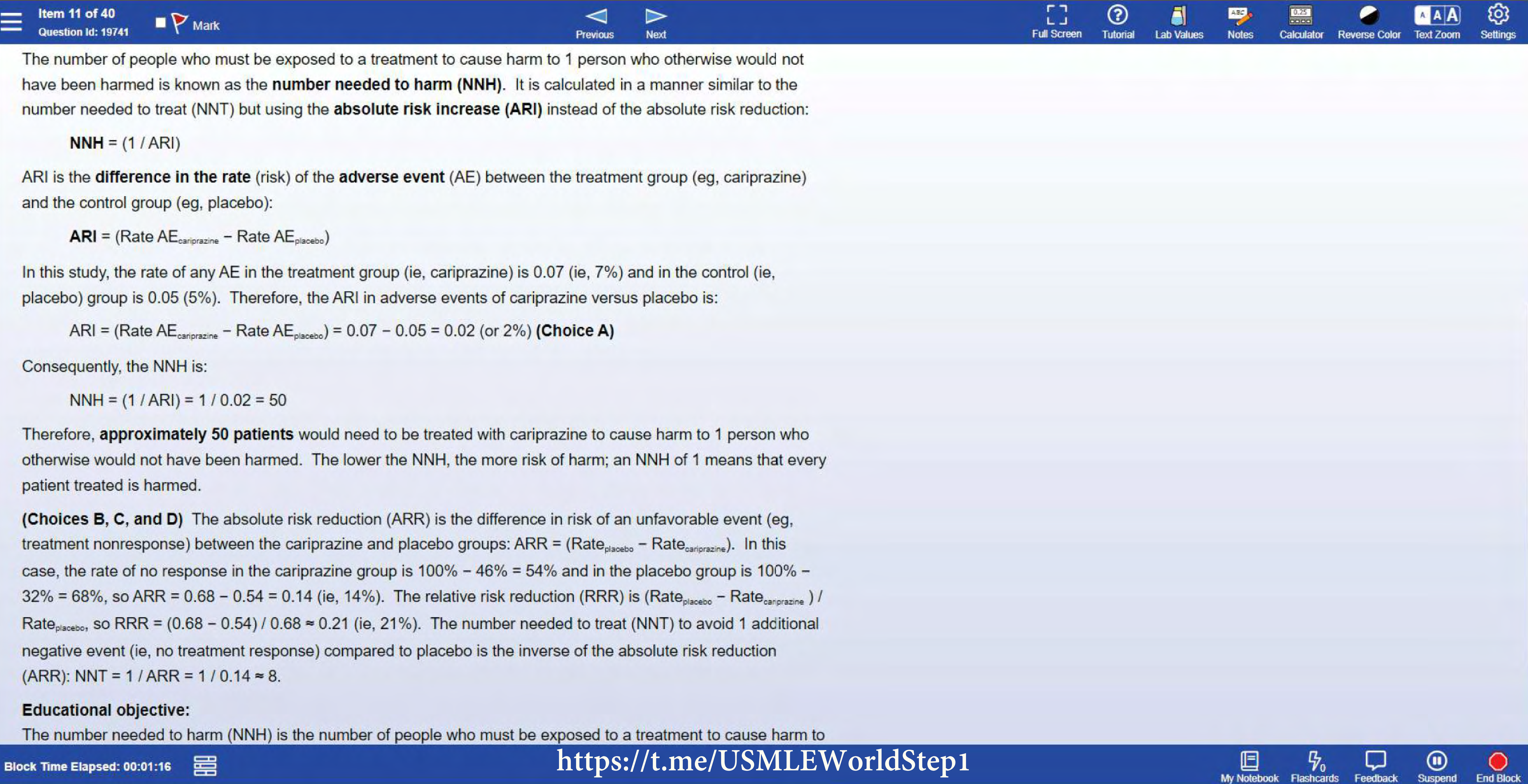
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ARI = $(\text{Rate AE}_{\text{cariprazine}} - \text{Rate AE}_{\text{placebo}})$

In this study, the rate of any AE in the treatment group (ie, cariprazine) is 0.07 (ie, 7%) and in the control (ie, placebo) group is 0.05 (5%). Therefore, the ARI in adverse events of cariprazine versus placebo is:

ARI = $(\text{Rate AE}_{\text{cariprazine}} - \text{Rate AE}_{\text{placebo}}) = 0.07 - 0.05 = 0.02$ (or 2%) **(Choice A)**

Consequently, the NNH is:

NNH = (1 / ARI) = 1 / 0.02 = 50

Therefore, **approximately 50 patients** would need to be treated with cariprazine to cause harm to 1 person who otherwise would not have been harmed. The lower the NNH, the more risk of harm; an NNH of 1 means that every patient treated is harmed.

(Choices B, C, and D) The absolute risk reduction (ARR) is the difference in risk of an unfavorable event (eg, treatment nonresponse) between the cariprazine and placebo groups: ARR = $(\text{Rate}_{\text{placebo}} - \text{Rate}_{\text{cariprazine}})$. In this case, the rate of no response in the cariprazine group is 100% − 46% = 54% and in the placebo group is 100% − 32% = 68%, so ARR = 0.68 − 0.54 = 0.14 (ie, 14%). The relative risk reduction (RRR) is $(\text{Rate}_{\text{placebo}} - \text{Rate}_{\text{cariprazine}}) / \text{Rate}_{\text{placebo}}$, so RRR = (0.68 − 0.54) / 0.68 ≈ 0.21 (ie, 21%). The number needed to treat (NNT) to avoid 1 additional negative event (ie, no treatment response) compared to placebo is the inverse of the absolute risk reduction (ARR): NNT = 1 / ARR = 1 / 0.14 ≈ 8.

Educational objective:

The number needed to harm (NNH) is the number of people who must be exposed to a treatment to cause harm to

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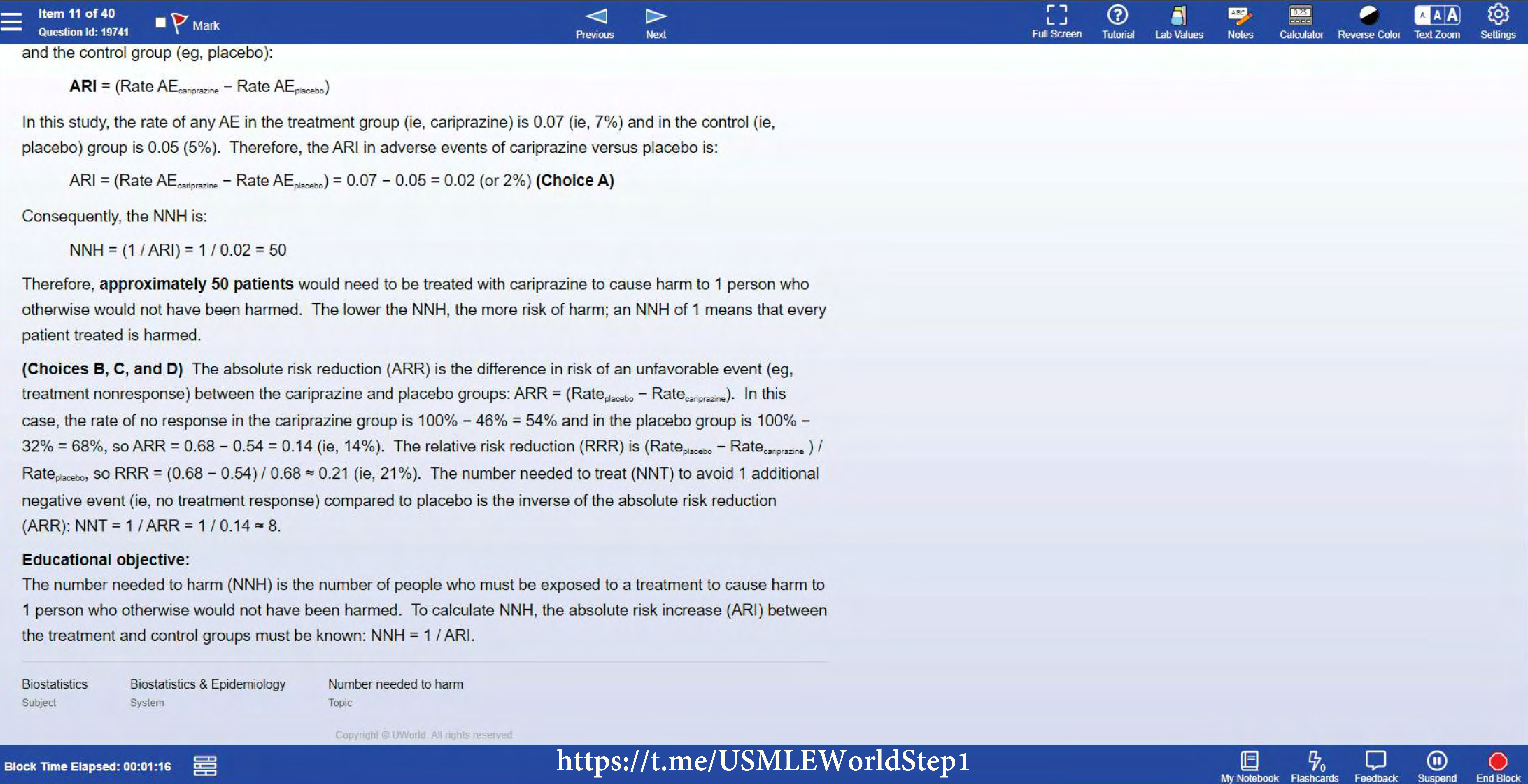
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and the control group (eg, placebo):

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In this study, the rate of any AE in the treatment group (ie, cariprazine) is 0.07 (ie, 7%) and in the control (ie, placebo) group is 0.05 (5%). Therefore, the ARI in adverse events of cariprazine versus placebo is:

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Educational objective:

The number needed to harm (NNH) is the number of people who must be exposed to a treatment to cause harm to 1 person who otherwise would not have been harmed. To calculate NNH, the absolute risk increase (ARI) between the treatment and control groups must be known: NNH = 1 / ARI.

Biostatistics	Biostatistics & Epidemiology	Number needed to harm
Subject	System	Topic

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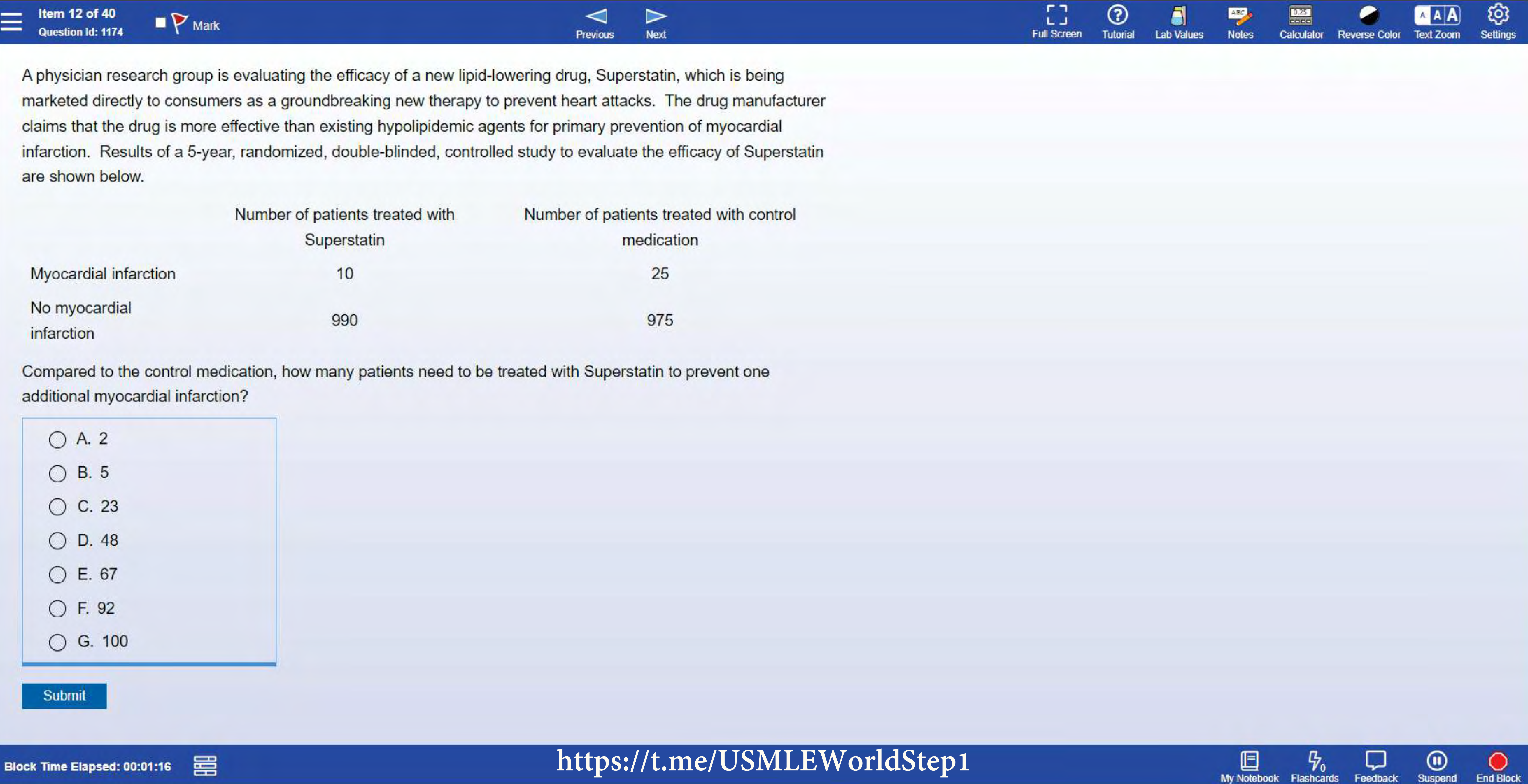
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A physician research group is evaluating the efficacy of a new lipid-lowering drug, Superstatin, which is being marketed directly to consumers as a groundbreaking new therapy to prevent heart attacks. The drug manufacturer claims that the drug is more effective than existing hypolipidemic agents for primary prevention of myocardial infarction. Results of a 5-year, randomized, double-blinded, controlled study to evaluate the efficacy of Superstatin are shown below.

	Number of patients treated with Superstatin	Number of patients treated with control medication
Myocardial infarction	10	25
No myocardial infarction	990	975

Compared to the control medication, how many patients need to be treated with Superstatin to prevent one additional myocardial infarction?

○ A. 2
○ B. 5
○ C. 23
○ D. 48
○ E. 67
○ F. 92
○ G. 100

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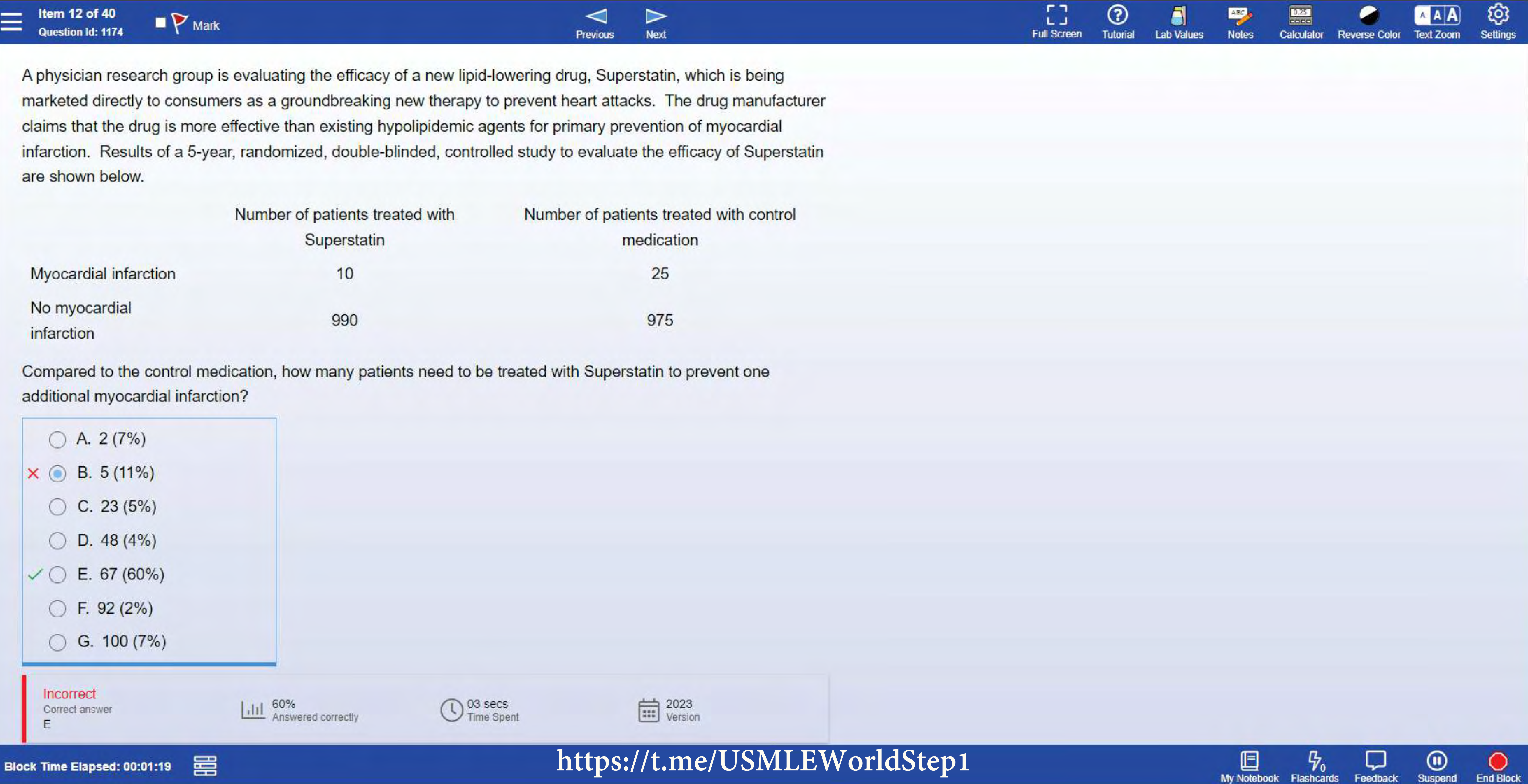
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- ○ A. 2 (7%)
- ✗ ● B. 5 (11%)
- ○ C. 23 (5%)
- ○ D. 48 (4%)
- ✓ ○ E. 67 (60%)
- ○ F. 92 (2%)
- ○ G. 100 (7%)

Incorrect
Correct answer
E

60%
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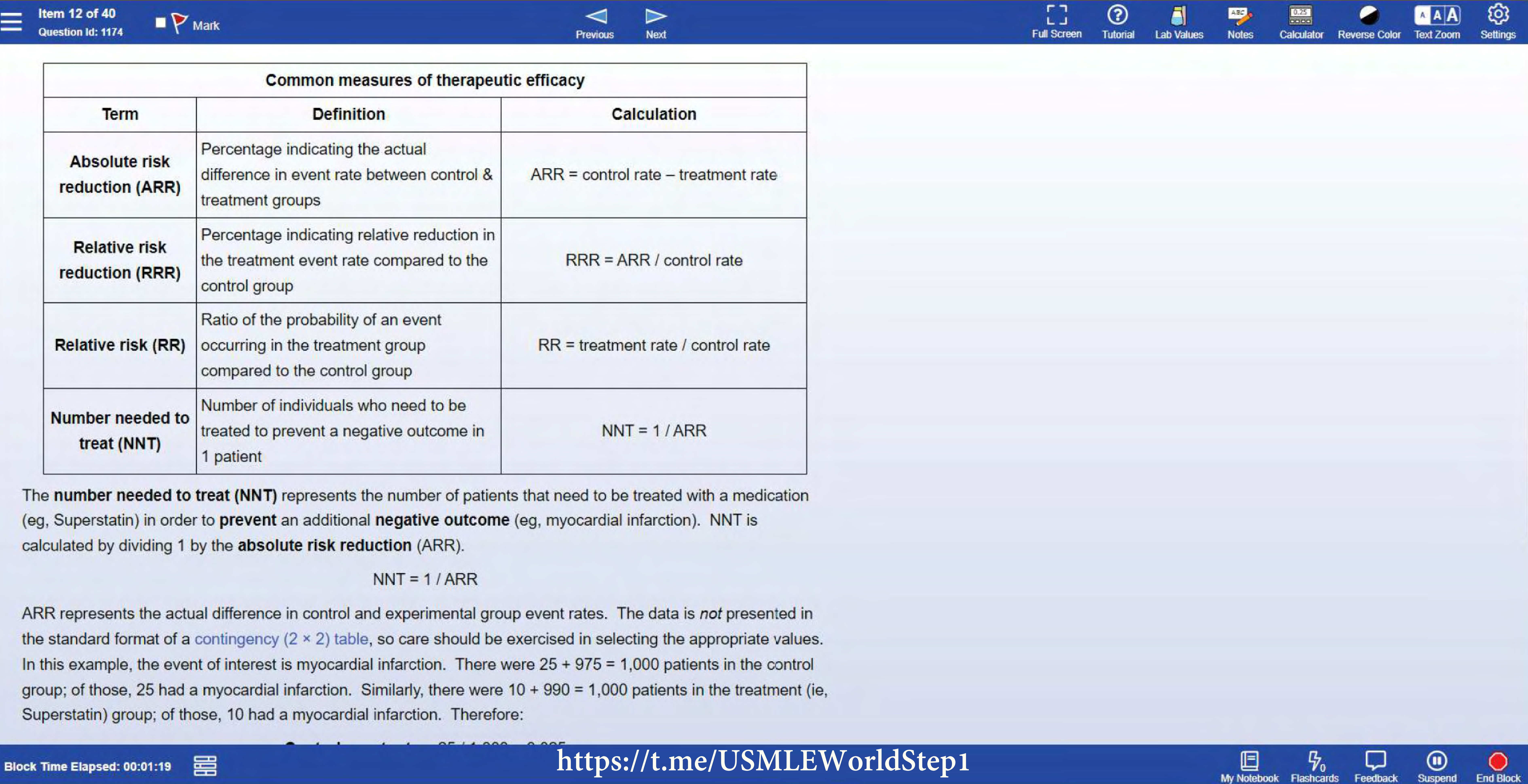
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Common measures of therapeutic efficacy

Term	Definition	Calculation
Absolute risk reduction (ARR)	Percentage indicating the actual difference in event rate between control & treatment groups	ARR = control rate – treatment rate
Relative risk reduction (RRR)	Percentage indicating relative reduction in the treatment event rate compared to the control group	RRR = ARR / control rate
Relative risk (RR)	Ratio of the probability of an event occurring in the treatment group compared to the control group	RR = treatment rate / control rate
Number needed to treat (NNT)	Number of individuals who need to be treated to prevent a negative outcome in 1 patient	NNT = 1 / ARR

The **number needed to treat (NNT)** represents the number of patients that need to be treated with a medication (eg, Superstatin) in order to **prevent** an additional **negative outcome** (eg, myocardial infarction). NNT is calculated by dividing 1 by the **absolute risk reduction** (ARR).

NNT = 1 / ARR

ARR represents the actual difference in control and experimental group event rates. The data is *not* presented in the standard format of a contingency (2 × 2) table, so care should be exercised in selecting the appropriate values. In this example, the event of interest is myocardial infarction. There were 25 + 975 = 1,000 patients in the control group; of those, 25 had a myocardial infarction. Similarly, there were 10 + 990 = 1,000 patients in the treatment (ie, Superstatin) group; of those, 10 had a myocardial infarction. Therefore:

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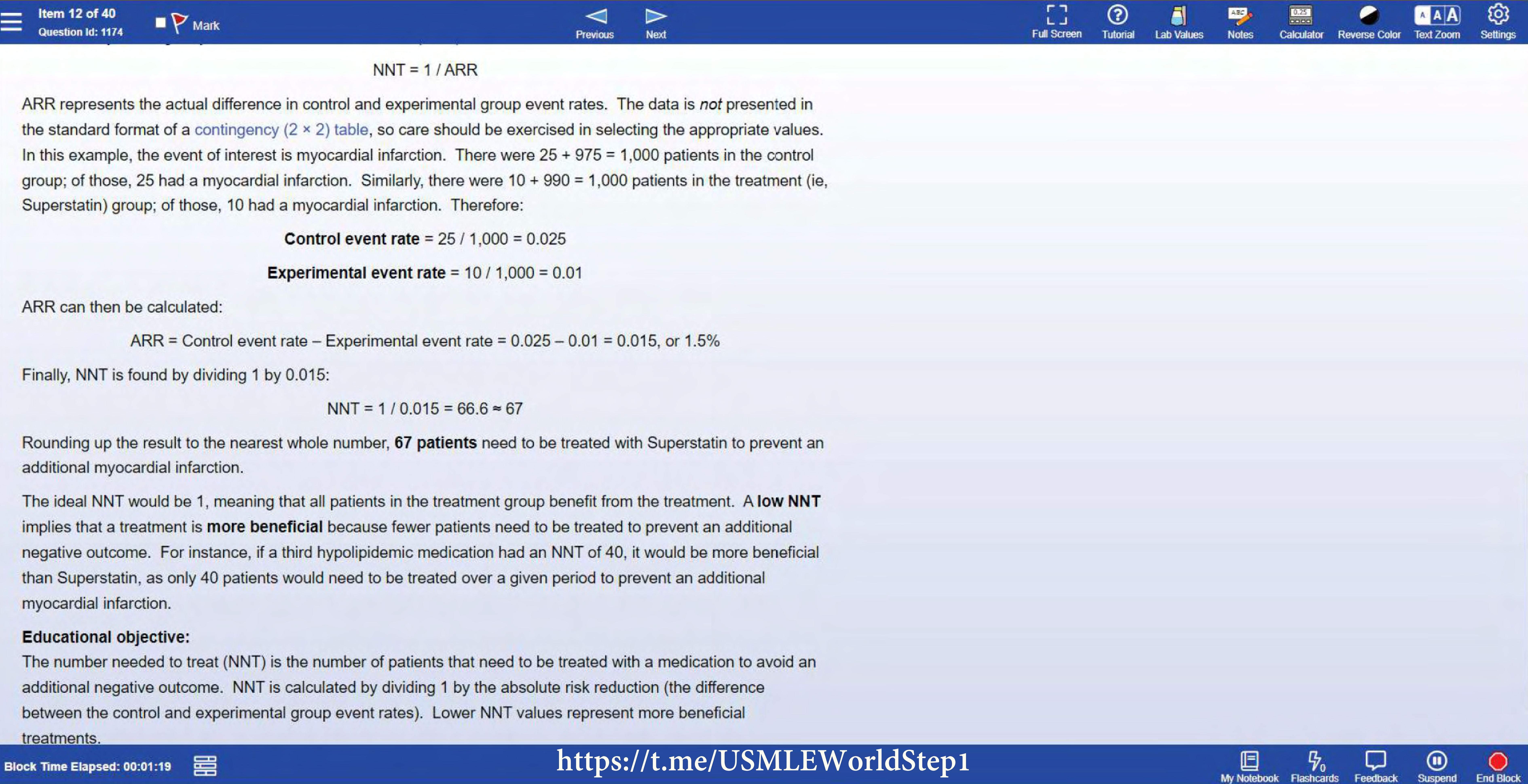
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$$NNT = 1 / ARR$$

ARR represents the actual difference in control and experimental group event rates. The data is *not* presented in the standard format of a contingency (2 × 2) table, so care should be exercised in selecting the appropriate values. In this example, the event of interest is myocardial infarction. There were 25 + 975 = 1,000 patients in the control group; of those, 25 had a myocardial infarction. Similarly, there were 10 + 990 = 1,000 patients in the treatment (ie, Superstatin) group; of those, 10 had a myocardial infarction. Therefore:

Control event rate = 25 / 1,000 = 0.025

Experimental event rate = 10 / 1,000 = 0.01

ARR can then be calculated:

ARR = Control event rate – Experimental event rate = 0.025 – 0.01 = 0.015, or 1.5%

Finally, NNT is found by dividing 1 by 0.015:

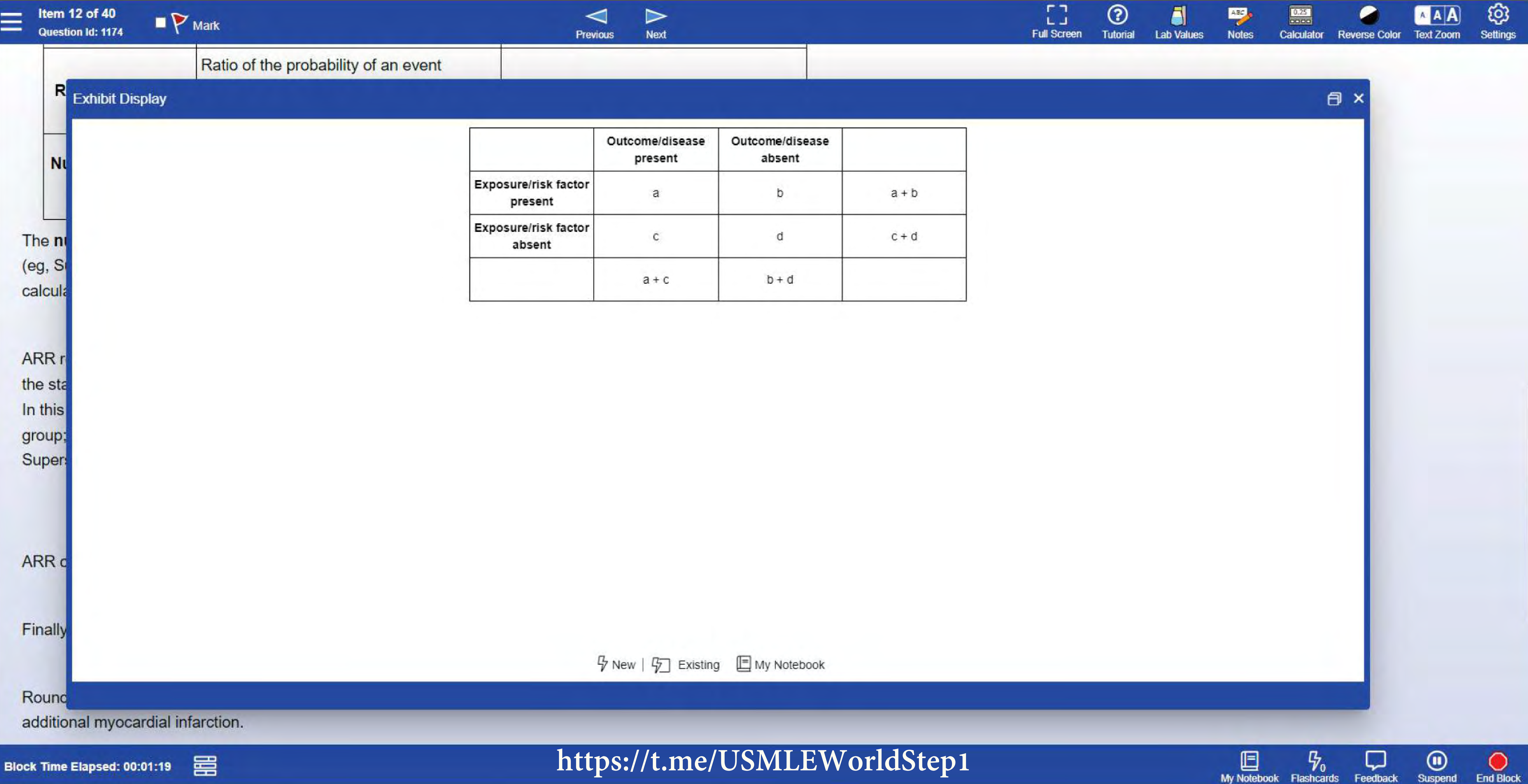
$$NNT = 1 / 0.015 = 66.6 \approx 67$$

Rounding up the result to the nearest whole number, **67 patients** need to be treated with Superstatin to prevent an additional myocardial infarction.

The ideal NNT would be 1, meaning that all patients in the treatment group benefit from the treatment. A **low NNT** implies that a treatment is **more beneficial** because fewer patients need to be treated to prevent an additional negative outcome. For instance, if a third hypolipidemic medication had an NNT of 40, it would be more beneficial than Superstatin, as only 40 patients would need to be treated over a given period to prevent an additional myocardial infarction.

Educational objective:

The number needed to treat (NNT) is the number of patients that need to be treated with a medication to avoid an additional negative outcome. NNT is calculated by dividing 1 by the absolute risk reduction (the difference between the control and experimental group event rates). Lower NNT values represent more beneficial treatments.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additional myocardial infarction.

	Outcome/disease present	Outcome/disease absent	
Exposure/risk factor present	a	b	a + b
Exposure/risk factor absent	c	d	c + d
	a + c	b + d	

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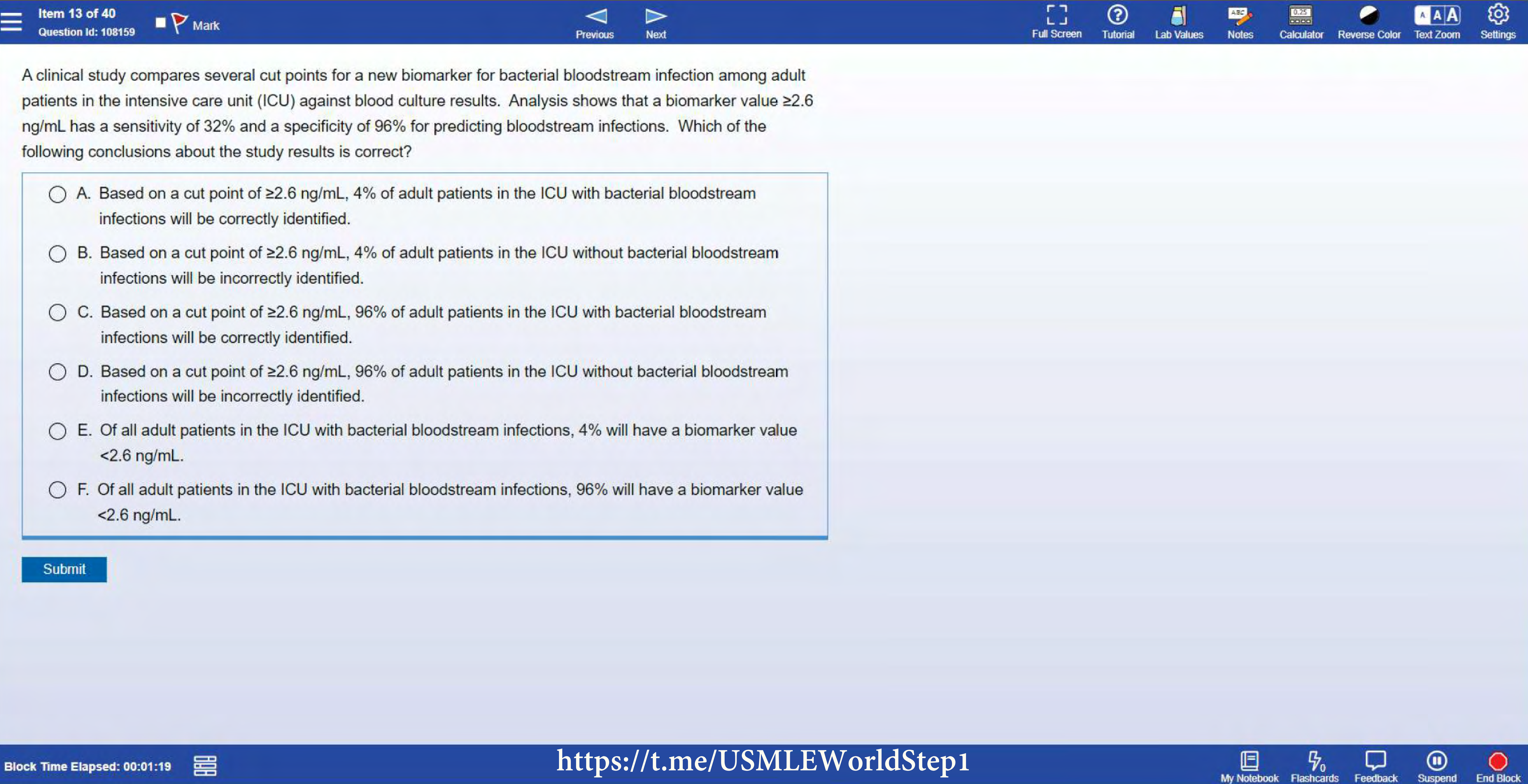
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Item 13 of 40
Question Id: 108159

A clinical study compares several cut points for a new biomarker for bacterial bloodstream infection among adult patients in the intensive care unit (ICU) against blood culture results. Analysis shows that a biomarker value ≥2.6 ng/mL has a sensitivity of 32% and a specificity of 96% for predicting bloodstream infections. Which of the following conclusions about the study results is correct?

- ○ A. Based on a cut point of ≥2.6 ng/mL, 4% of adult patients in the ICU with bacterial bloodstream infections will be correctly identified.
- ○ B. Based on a cut point of ≥2.6 ng/mL, 4% of adult patients in the ICU without bacterial bloodstream infections will be incorrectly identified.
- ○ C. Based on a cut point of ≥2.6 ng/mL, 96% of adult patients in the ICU with bacterial bloodstream infections will be correctly identified.
- ○ D. Based on a cut point of ≥2.6 ng/mL, 96% of adult patients in the ICU without bacterial bloodstream infections will be incorrectly identified.
- ○ E. Of all adult patients in the ICU with bacterial bloodstream infections, 4% will have a biomarker value <2.6 ng/mL.
- ○ F. Of all adult patients in the ICU with bacterial bloodstream infections, 96% will have a biomarker value <2.6 ng/mL.

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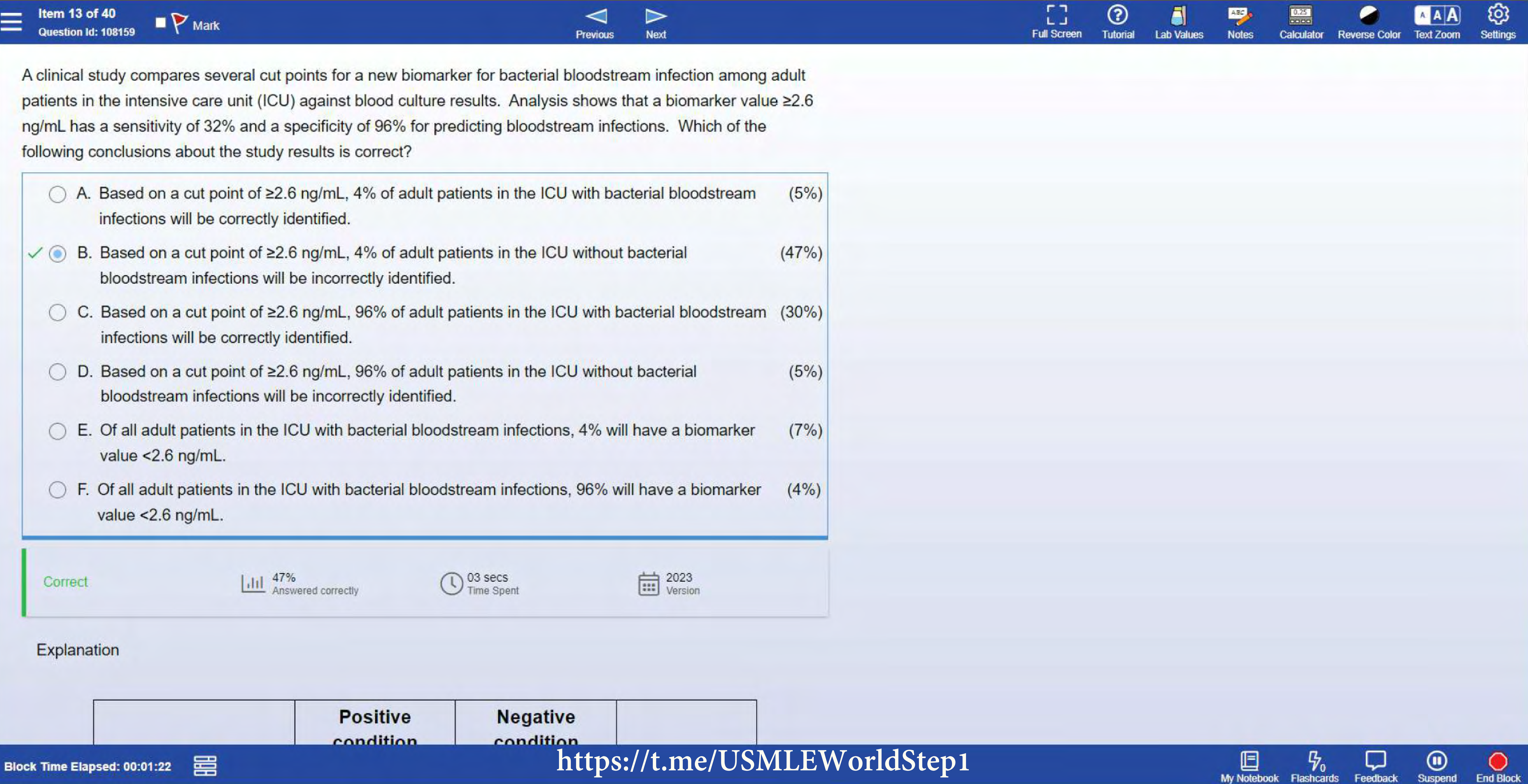
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A clinical study compares several cut points for a new biomarker for bacterial bloodstream infection among adult patients in the intensive care unit (ICU) against blood culture results. Analysis shows that a biomarker value ≥2.6 ng/mL has a sensitivity of 32% and a specificity of 96% for predicting bloodstream infections. Which of the following conclusions about the study results is correct?

○ A. Based on a cut point of ≥2.6 ng/mL, 4% of adult patients in the ICU with bacterial bloodstream infections will be correctly identified. (5%)

✓ ● B. Based on a cut point of ≥2.6 ng/mL, 4% of adult patients in the ICU without bacterial bloodstream infections will be incorrectly identified. (47%)

○ C. Based on a cut point of ≥2.6 ng/mL, 96% of adult patients in the ICU with bacterial bloodstream infections will be correctly identified. (30%)

○ D. Based on a cut point of ≥2.6 ng/mL, 96% of adult patients in the ICU without bacterial bloodstream infections will be incorrectly identified. (5%)

○ E. Of all adult patients in the ICU with bacterial bloodstream infections, 4% will have a biomarker value <2.6 ng/mL. (7%)

○ F. Of all adult patients in the ICU with bacterial bloodstream infections, 96% will have a biomarker value <2.6 ng/mL. (4%)

Correct

47%
Answered correctly

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Explanation

	Positive condition	Negative condition	

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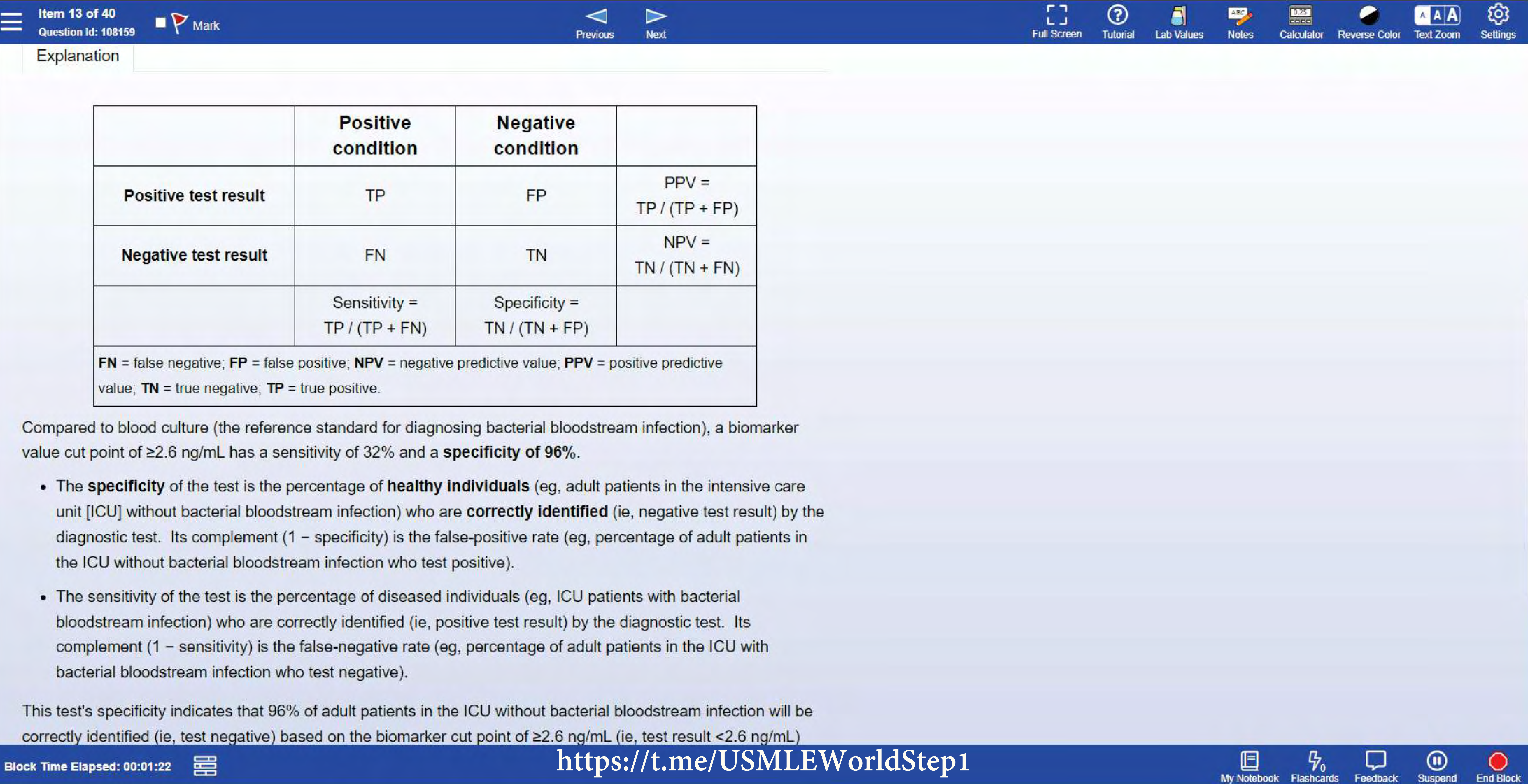
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Explanation

	Positive condition	Negative condition	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

Compared to blood culture (the reference standard for diagnosing bacterial bloodstream infection), a biomarker value cut point of ≥2.6 ng/mL has a sensitivity of 32% and a **specificity of 96%**.

- The **specificity** of the test is the percentage of **healthy individuals** (eg, adult patients in the intensive care unit [ICU] without bacterial bloodstream infection) who are **correctly identified** (ie, negative test result) by the diagnostic test. Its complement (1 − specificity) is the false-positive rate (eg, percentage of adult patients in the ICU without bacterial bloodstream infection who test positive).
- The sensitivity of the test is the percentage of diseased individuals (eg, ICU patients with bacterial bloodstream infection) who are correctly identified (ie, positive test result) by the diagnostic test. Its complement (1 − sensitivity) is the false-negative rate (eg, percentage of adult patients in the ICU with bacterial bloodstream infection who test negative).

This test's specificity indicates that 96% of adult patients in the ICU without bacterial bloodstream infection will be correctly identified (ie, test negative) based on the biomarker cut point of ≥2.6 ng/mL (ie, test result <2.6 ng/mL)

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value; TN = true negative; TP = true positive.

Compared to blood culture (the reference standard for diagnosing bacterial bloodstream infection), a biomarker value cut point of ≥2.6 ng/mL has a sensitivity of 32% and a **specificity of 96%**.

- The **specificity** of the test is the percentage of **healthy individuals** (eg, adult patients in the intensive care unit [ICU] without bacterial bloodstream infection) who are **correctly identified** (ie, negative test result) by the diagnostic test. Its complement (1 − specificity) is the false-positive rate (eg, percentage of adult patients in the ICU without bacterial bloodstream infection who test positive).
- The sensitivity of the test is the percentage of diseased individuals (eg, ICU patients with bacterial bloodstream infection) who are correctly identified (ie, positive test result) by the diagnostic test. Its complement (1 − sensitivity) is the false-negative rate (eg, percentage of adult patients in the ICU with bacterial bloodstream infection who test negative).

This test's specificity indicates that 96% of adult patients in the ICU without bacterial bloodstream infection will be correctly identified (ie, test negative) based on the biomarker cut point of ≥2.6 ng/mL (ie, test result <2.6 ng/mL) **(Choice D)**. Conversely, 100% − 96% = **4%** of adult patients in the ICU **without** bacterial bloodstream infection will be **incorrectly identified**.

(Choices A, C, E, and F) This test's sensitivity indicates that 32% of adult patients in the ICU with bacterial bloodstream infection will be correctly diagnosed (ie, test positive) based on the biomarker cut point of ≥2.6 ng/mL. Conversely, 100% − 32% = 68% of adult patients in the ICU with bacterial bloodstream infection will be missed (ie, test negative with a result <2.6 ng/mL).

Educational objective:

Sensitivity represents the probability that an individual with disease will have a positive test result. Specificity represents the probability that an individual without disease will have a negative test result.

Biostatistics	Biostatistics & Epidemiology	Sensitivity and specificity
Subject	System	Topic

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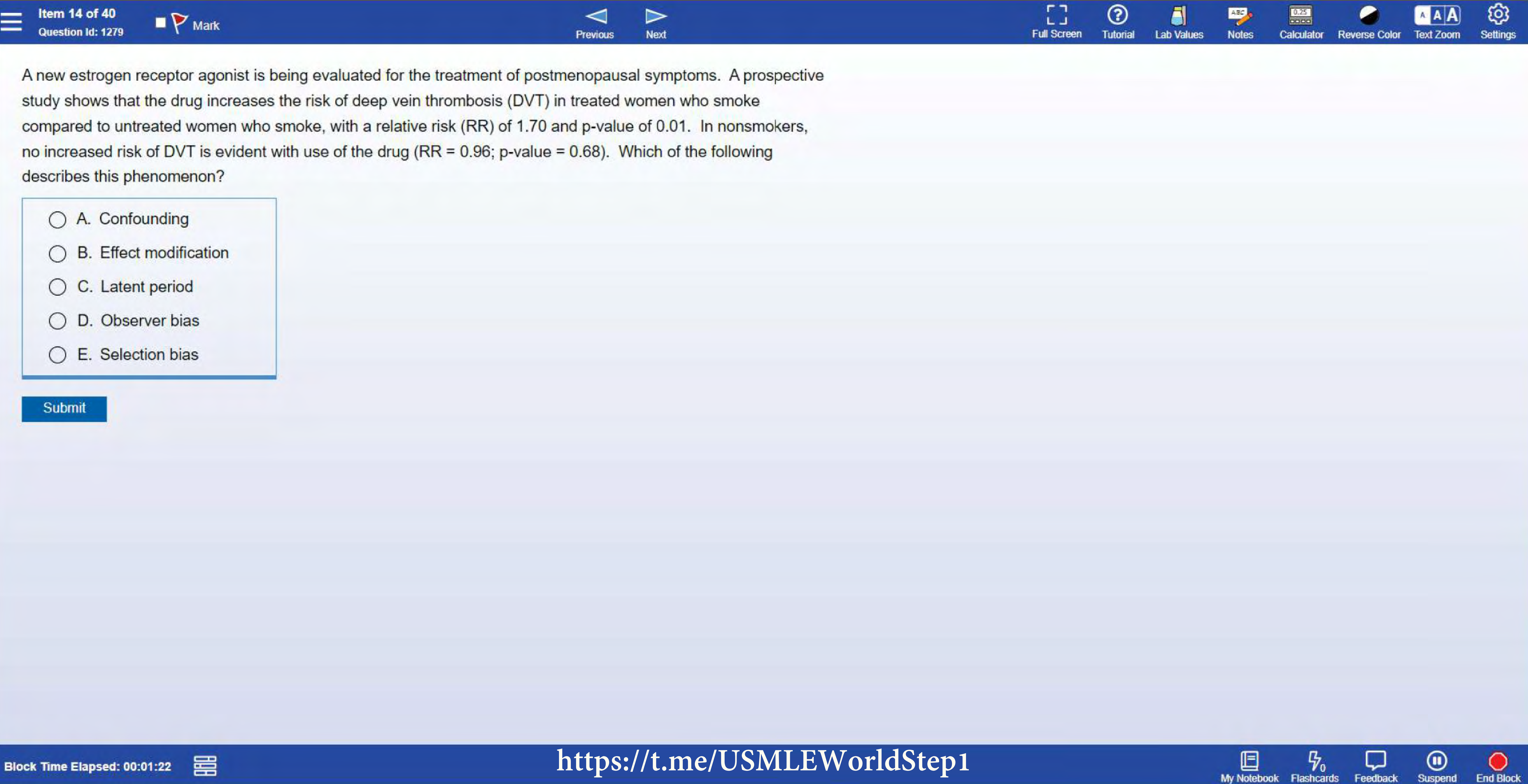
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Question Id: 1279

A new estrogen receptor agonist is being evaluated for the treatment of postmenopausal symptoms. A prospective study shows that the drug increases the risk of deep vein thrombosis (DVT) in treated women who smoke compared to untreated women who smoke, with a relative risk (RR) of 1.70 and p-value of 0.01. In nonsmokers, no increased risk of DVT is evident with use of the drug (RR = 0.96; p-value = 0.68). Which of the following describes this phenomenon?

- ○ A. Confounding
- ○ B. Effect modification
- ○ C. Latent period
- ○ D. Observer bias
- ○ E. Selection bias

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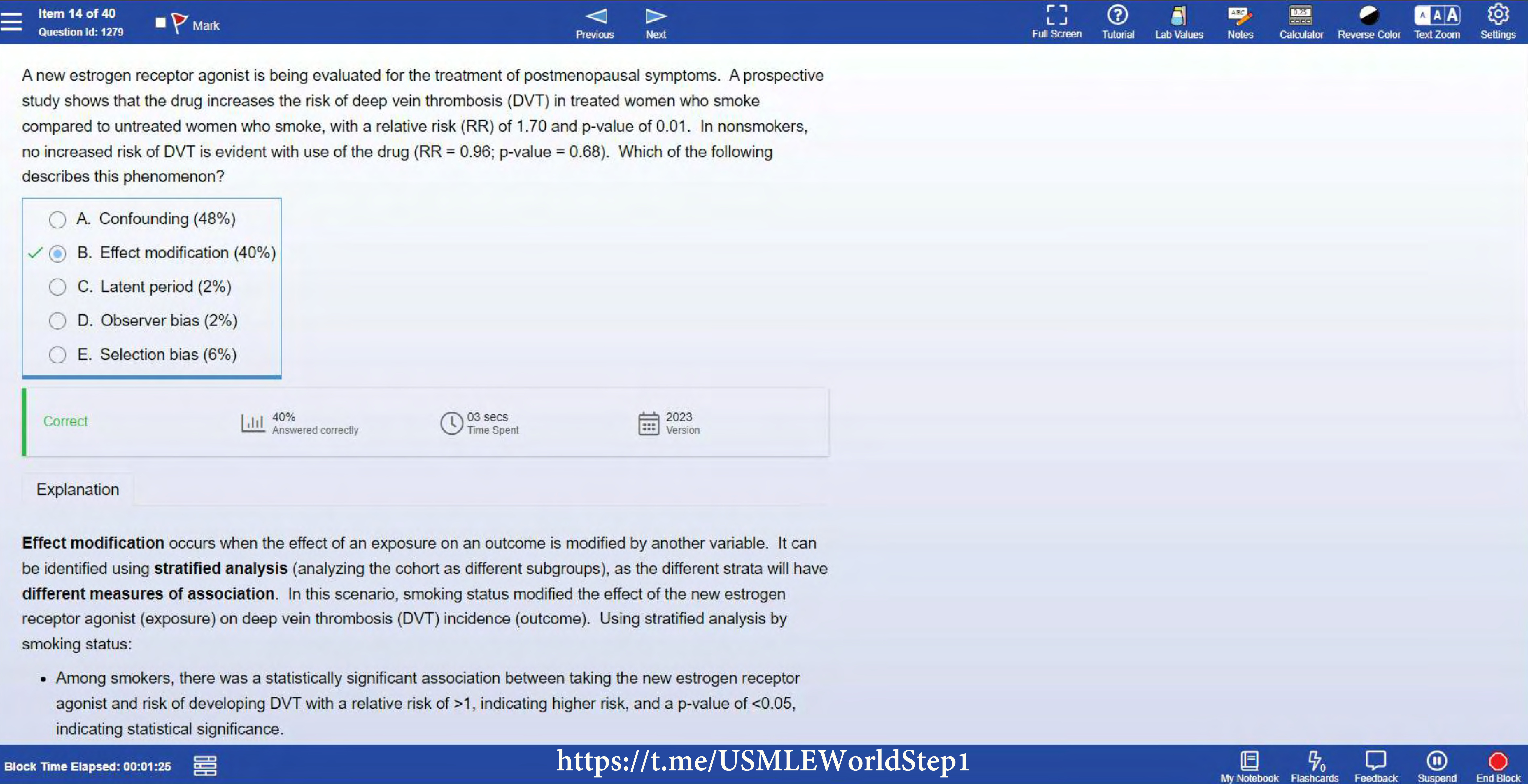
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- ○ A. Confounding (48%)
- ✓ ● B. Effect modification (40%)
- ○ C. Latent period (2%)
- ○ D. Observer bias (2%)
- ○ E. Selection bias (6%)

Correct

40% Answered correctly

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Explanation

Effect modification occurs when the effect of an exposure on an outcome is modified by another variable. It can be identified using **stratified analysis** (analyzing the cohort as different subgroups), as the different strata will have **different measures of association**. In this scenario, smoking status modified the effect of the new estrogen receptor agonist (exposure) on deep vein thrombosis (DVT) incidence (outcome). Using stratified analysis by smoking status:

- Among smokers, there was a statistically significant association between taking the new estrogen receptor agonist and risk of developing DVT with a relative risk of >1, indicating higher risk, and a p-value of <0.05, indicating statistical significance.

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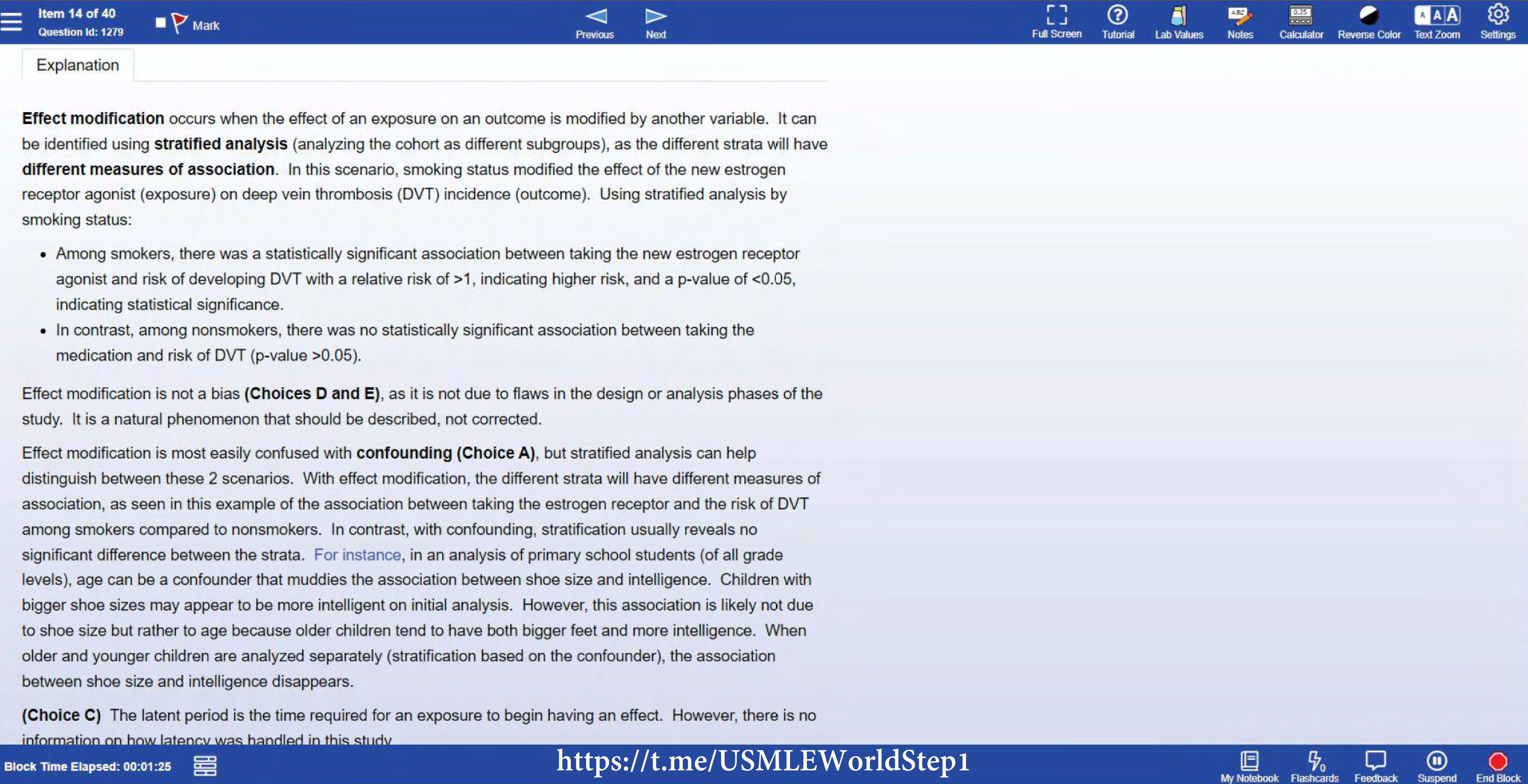

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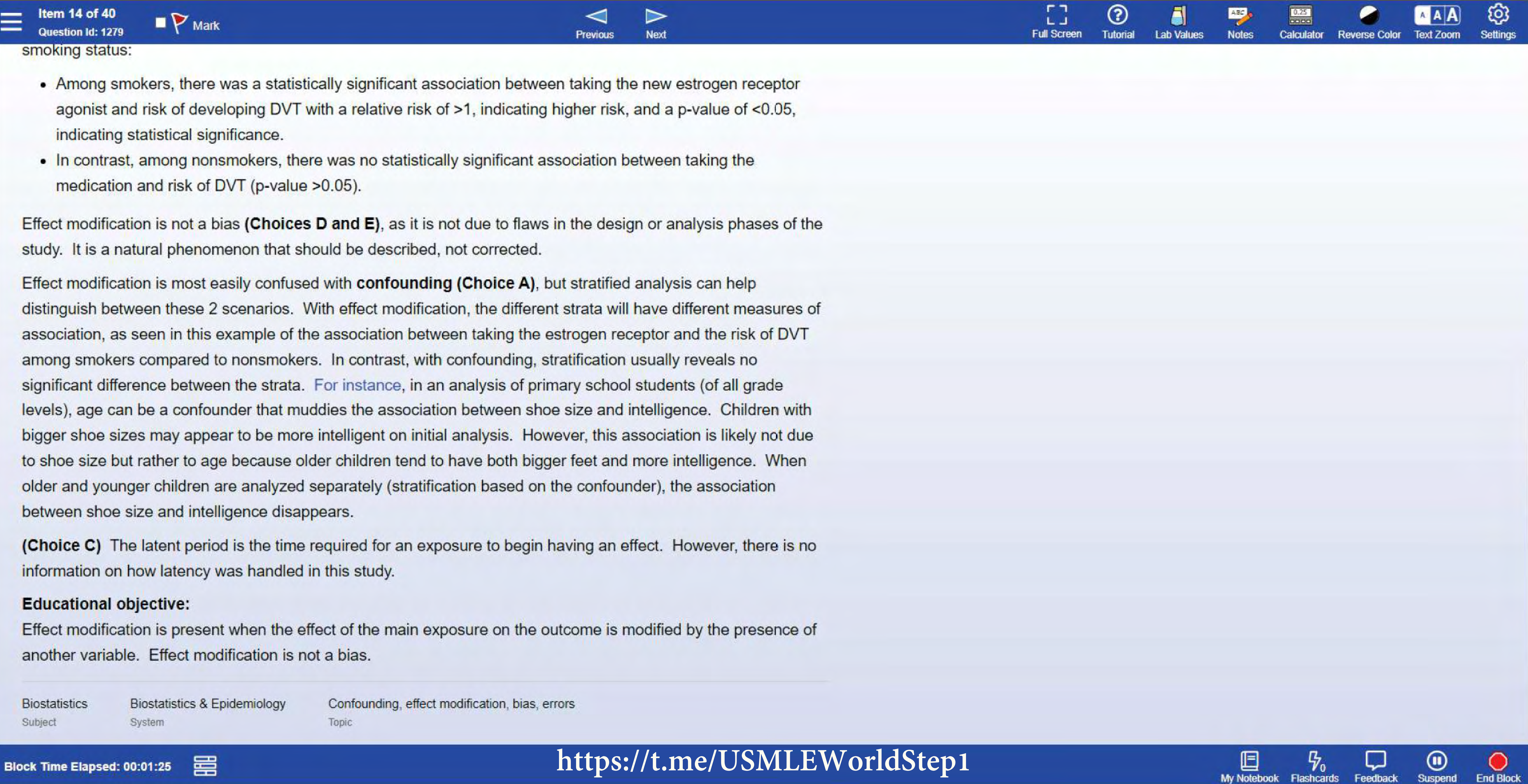
- In contrast, among nonsmokers, there was no statistically significant association between taking the medication and risk of DVT (p-value >0.05).

Effect modification is not a bias **(Choices D and E)**, as it is not due to flaws in the design or analysis phases of the study. It is a natural phenomenon that should be described, not corrected.

Effect modification is most easily confused with **confounding (Choice A)**, but stratified analysis can help distinguish between these 2 scenarios. With effect modification, the different strata will have different measures of association, as seen in this example of the association between taking the estrogen receptor and the risk of DVT among smokers compared to nonsmokers. In contrast, with confounding, stratification usually reveals no significant difference between the strata. For instance, in an analysis of primary school students (of all grade levels), age can be a confounder that muddies the association between shoe size and intelligence. Children with bigger shoe sizes may appear to be more intelligent on initial analysis. However, this association is likely not due to shoe size but rather to age because older children tend to have both bigger feet and more intelligence. When older and younger children are analyzed separately (stratification based on the confounder), the association between shoe size and intelligence disappears.

(Choice C) The latent period is the time required for an exposure to begin having an effect. However, there is no information on how latency was handled in this study.



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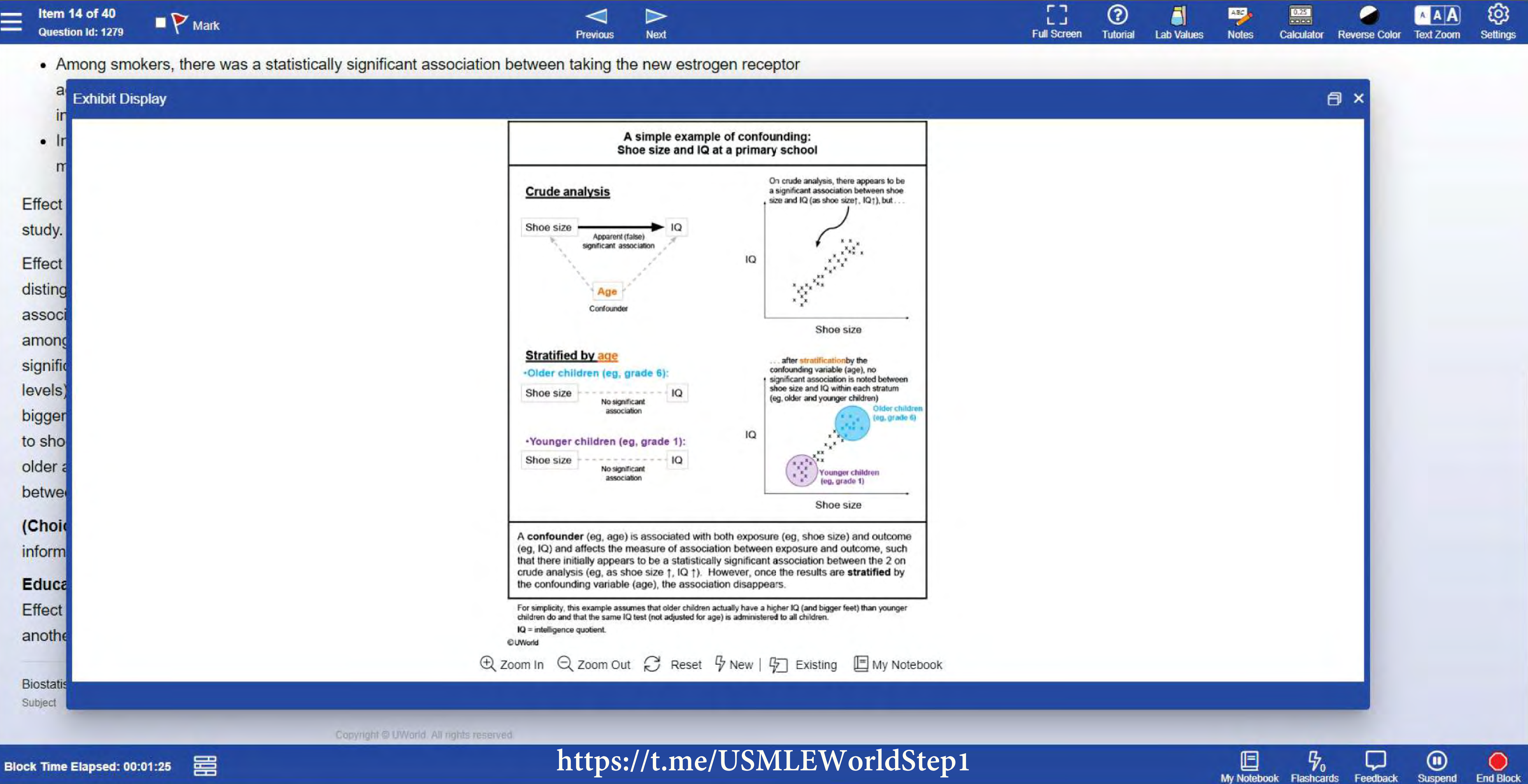
(Choice C) The latent period is the time required for an exposure to begin having an effect. However, there is no information on how latency was handled in this study.

Educational objective:

Effect modification is present when the effect of the main exposure on the outcome is modified by the presence of another variable. Effect modification is not a bias.

Biostatistics	Biostatistics & Epidemiology	Confounding, effect modification, bias, errors
Subject	System	Topic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A simple example of confounding: Shoe size and IQ at a primary school

Crude analysis

Shoe size
IQ
Apparent (false) significant association
Age
Confounder

On crude analysis, there appears to be a significant association between shoe size and IQ (as shoe size↑, IQ↑), but . . .

IQ
Shoe size

Stratified by age

•Older children (eg, grade 6):

Shoe size
IQ
No significant association

•Younger children (eg, grade 1):

Shoe size
IQ
No significant association

. . . after stratificationby the confounding variable (age), no significant association is noted between shoe size and IQ within each stratum (eg, older and younger children)

Older children (eg, grade 6)
Younger children (eg, grade 1)
IQ
Shoe size

A **confounder** (eg, age) is associated with both exposure (eg, shoe size) and outcome (eg, IQ) and affects the measure of association between exposure and outcome, such that there initially appears to be a statistically significant association between the 2 on crude analysis (eg, as shoe size ↑, IQ ↑). However, once the results are **stratified** by the confounding variable (age), the association disappears.

For simplicity, this example assumes that older children actually have a higher IQ (and bigger feet) than younger children do and that the same IQ test (not adjusted for age) is administered to all children.

IQ = intelligence quotient.

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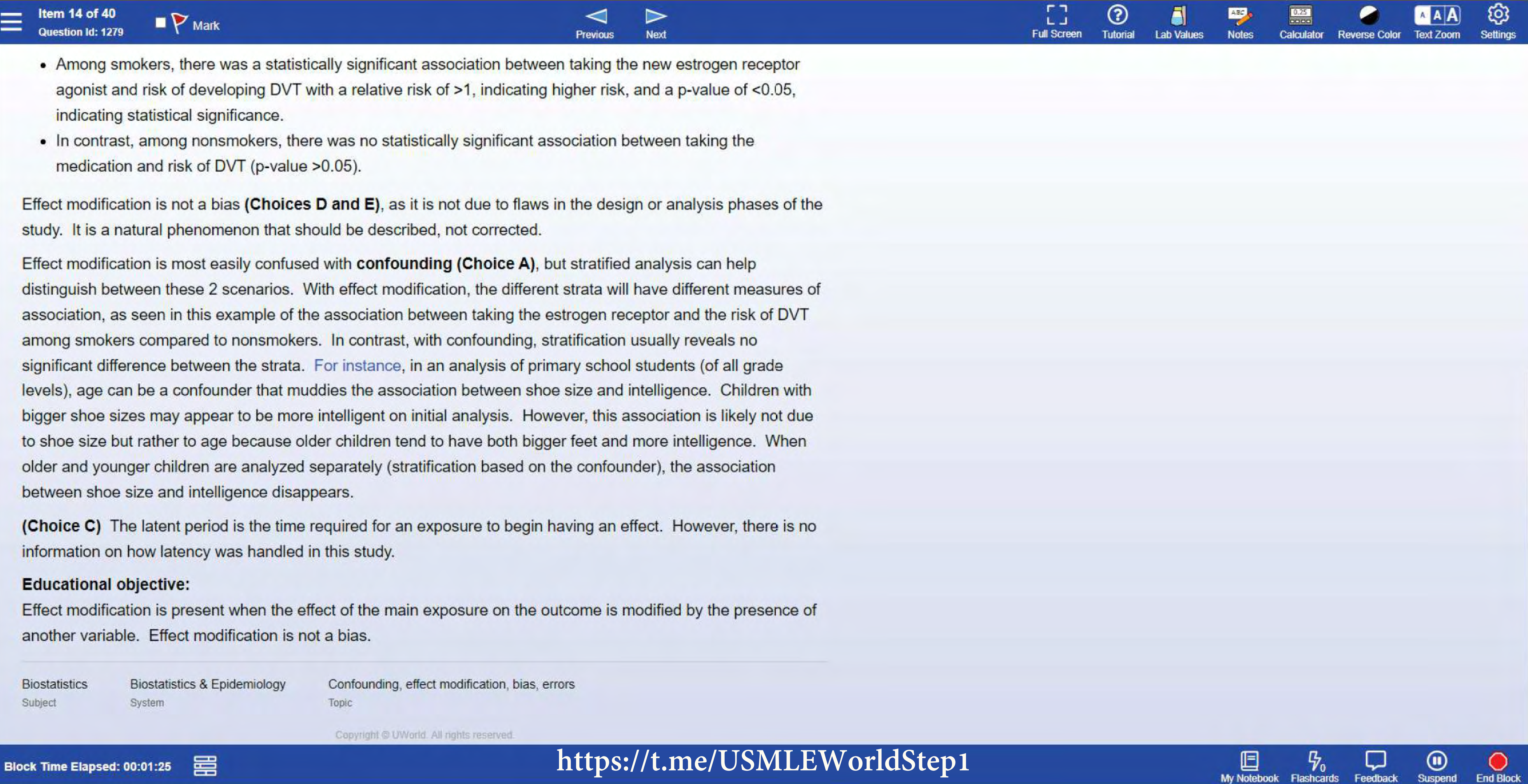

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(Choice C) The latent period is the time required for an exposure to begin having an effect. However, there is no information on how latency was handled in this study.

Educational objective:
Effect modification is present when the effect of the main exposure on the outcome is modified by the presence of another variable. Effect modification is not a bias.

Biostatistics	Biostatistics & Epidemiology	Confounding, effect modification, bias, errors
Subject	System	Topic

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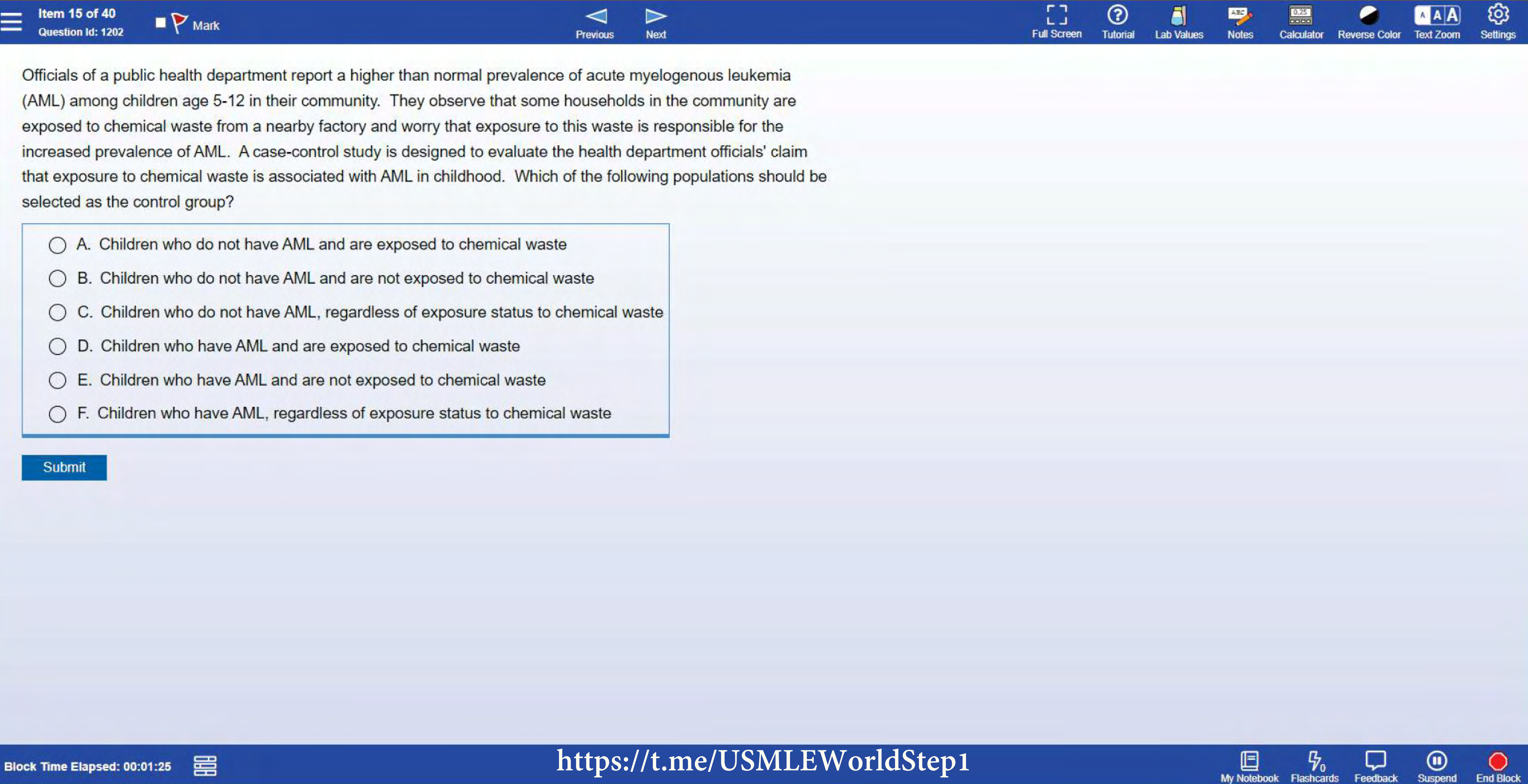
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Officials of a public health department report a higher than normal prevalence of acute myelogenous leukemia (AML) among children age 5-12 in their community. They observe that some households in the community are exposed to chemical waste from a nearby factory and worry that exposure to this waste is responsible for the increased prevalence of AML. A case-control study is designed to evaluate the health department officials' claim that exposure to chemical waste is associated with AML in childhood. Which of the following populations should be selected as the control group?

○ A. Children who do not have AML and are exposed to chemical waste
○ B. Children who do not have AML and are not exposed to chemical waste
○ C. Children who do not have AML, regardless of exposure status to chemical waste
○ D. Children who have AML and are exposed to chemical waste
○ E. Children who have AML and are not exposed to chemical waste
○ F. Children who have AML, regardless of exposure status to chemical waste

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✗ ● A. Children who do not have AML and are exposed to chemical waste (19%)
○ B. Children who do not have AML and are not exposed to chemical waste (20%)
✓ ○ C. Children who do not have AML, regardless of exposure status to chemical waste (30%)
○ D. Children who have AML and are exposed to chemical waste (0%)
○ E. Children who have AML and are not exposed to chemical waste (23%)
○ F. Children who have AML, regardless of exposure status to chemical waste (4%)

Incorrect
Correct answer
C

30%
Answered correctly

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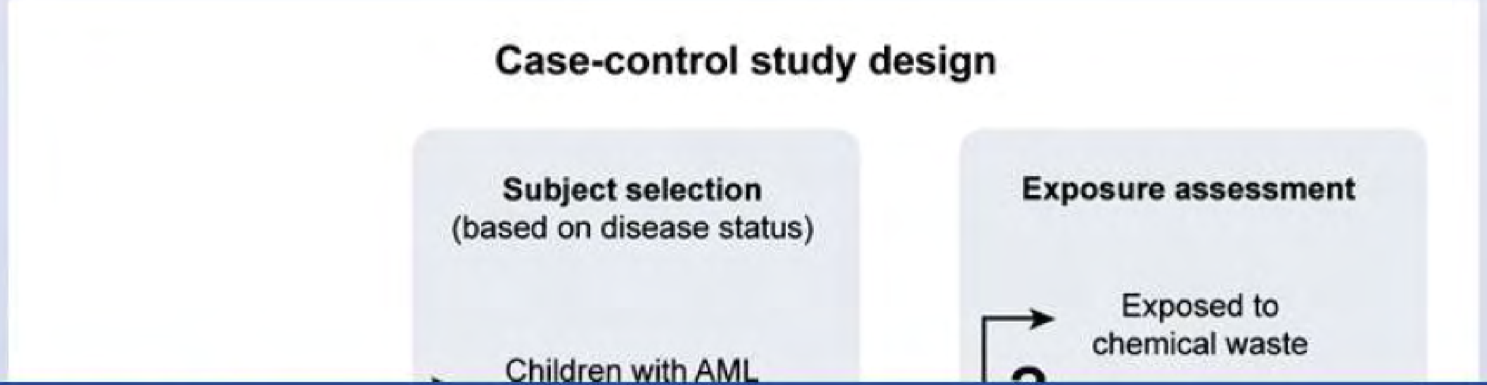
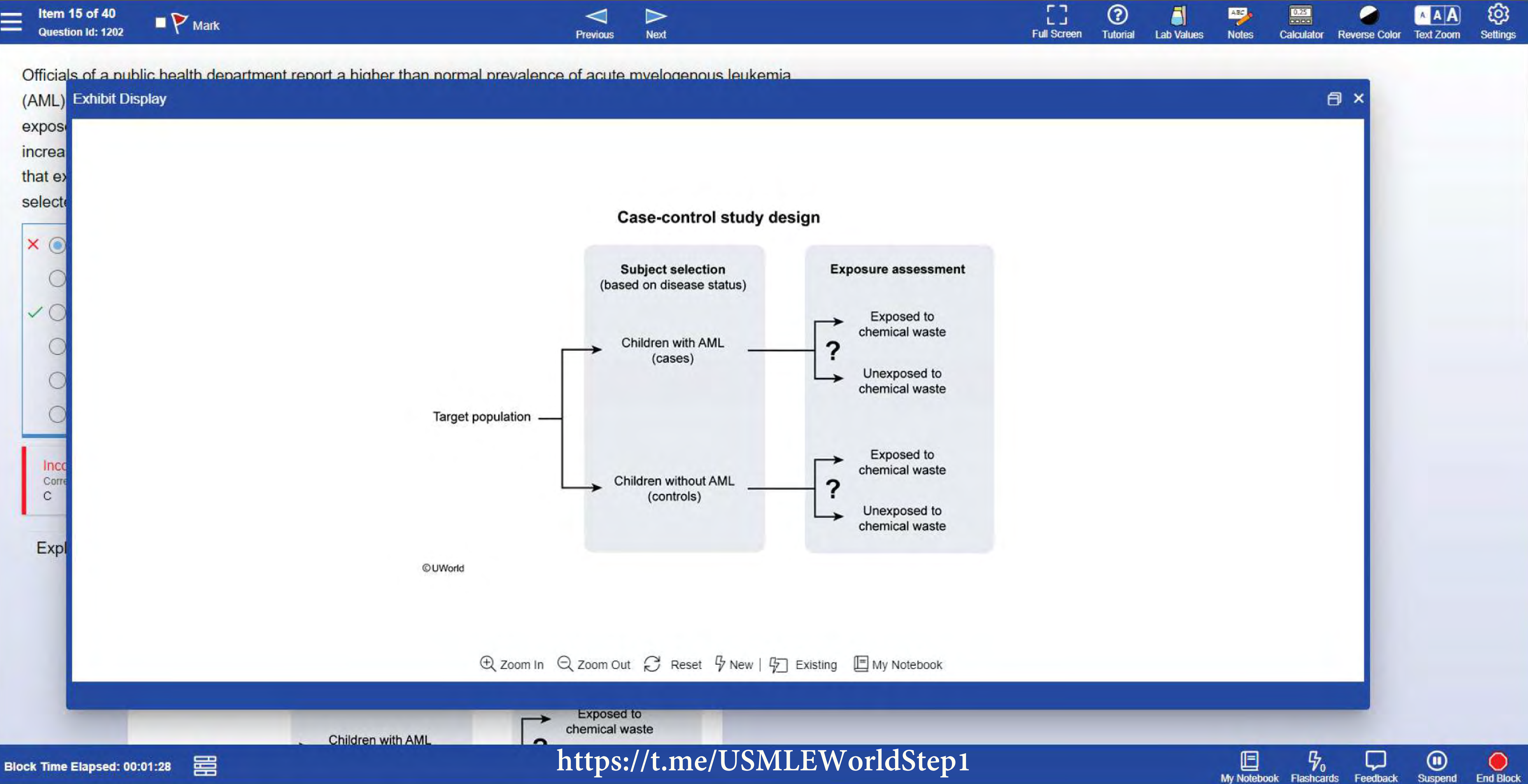
Explanation

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Officials of a public health department report a higher than normal prevalence of acute myelogenous leukemia (AML)

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Case-control study design

Subject selection
(based on disease status)
Exposure assessment
Target population
Children with AML
(cases)
Children without AML
(controls)
?
Exposed to chemical waste
Unexposed to chemical waste
?
Exposed to chemical waste
Unexposed to chemical waste

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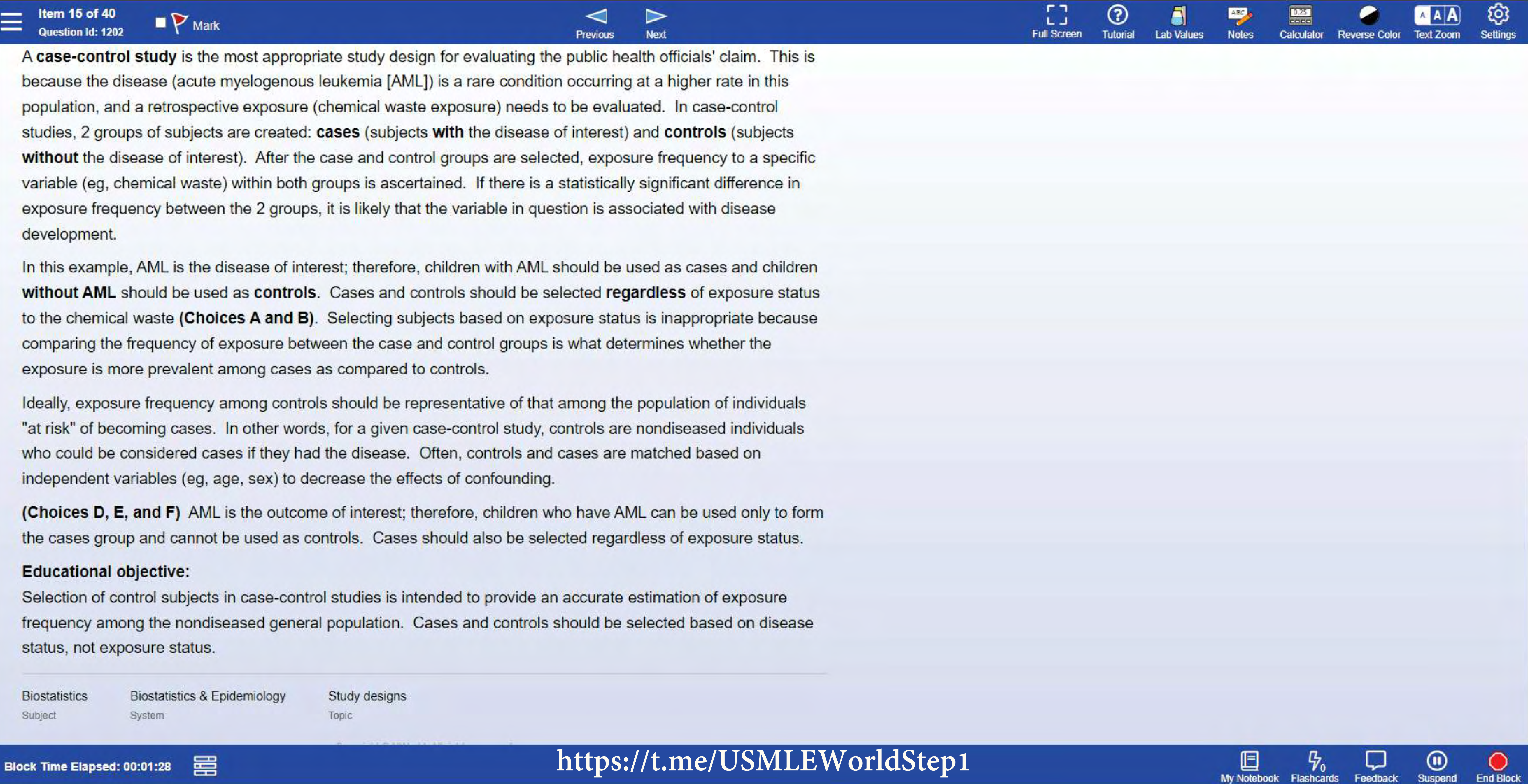


A **case-control study** is the most appropriate study design for evaluating the public health officials' claim. This is because the disease (acute myelogenous leukemia [AML]) is a rare condition occurring at a higher rate in this population, and a retrospective exposure (chemical waste exposure) needs to be evaluated. In case-control studies, 2 groups of subjects are created: **cases** (subjects **with** the disease of interest) and **controls** (subjects **without** the disease of interest). After the case and control groups are selected, exposure frequency to a specific variable (eg, chemical waste) within both groups is ascertained. If there is a statistically significant difference in exposure frequency between the 2 groups, it is likely that the variable in question is associated with disease development.

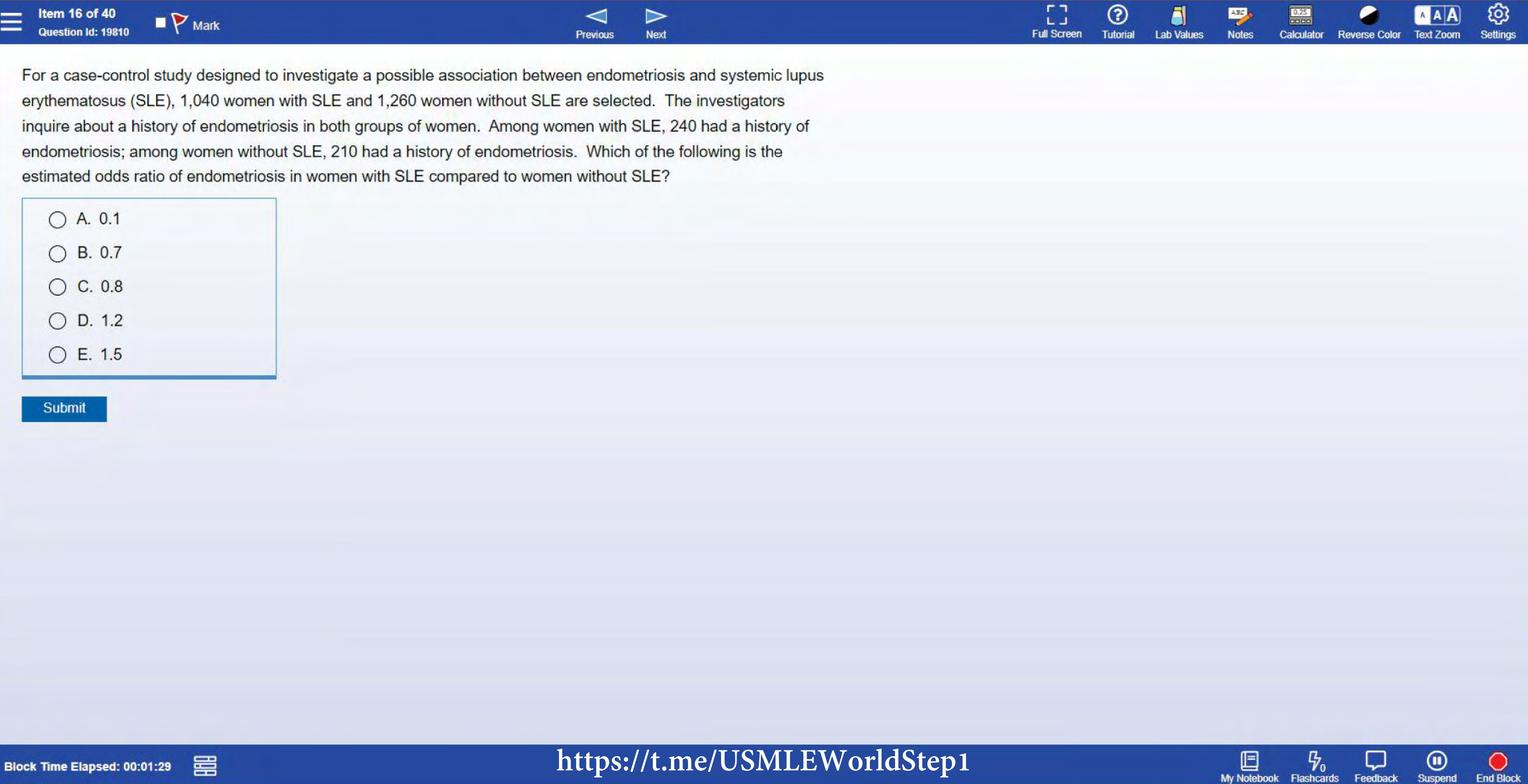
In this example, AML is the disease of interest; therefore, children with AML should be used as cases and children **without AML** should be used as **controls**. Cases and controls should be selected **regardless** of exposure status to the chemical waste **(Choices A and B)**. Selecting subjects based on exposure status is inappropriate because comparing the frequency of exposure between the case and control groups is what determines whether the exposure is more prevalent among cases as compared to controls.

Ideally, exposure frequency among controls should be representative of that among the population of individuals "at risk" of becoming cases. In other words, for a given case-control study, controls are nondiseased individuals who could be considered cases if they had the disease. Often, controls and cases are matched based on independent variables (eg, age, sex) to decrease the effects of confounding.

(Choices D, E, and F) AML is the outcome of interest; therefore, children who have AML can be used only to form the cases group and cannot be used as controls. Cases should also be selected regardless of exposure status.

Educational objective:
Selection of control subjects in case-control studies is intended to provide an accurate estimation of exposure frequency among the nondiseased general population. Cases and controls should be selected based on disease status, not exposure status.

Biostatistics	Biostatistics & Epidemiology	Study designs
Subject	System	Topic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For a case-control study designed to investigate a possible association between endometriosis and systemic lupus erythematosus (SLE), 1,040 women with SLE and 1,260 women without SLE are selected. The investigators inquire about a history of endometriosis in both groups of women. Among women with SLE, 240 had a history of endometriosis; among women without SLE, 210 had a history of endometriosis. Which of the following is the estimated odds ratio of endometriosis in women with SLE compared to women without SLE?

- ○ A. 0.1
- ○ B. 0.7
- ○ C. 0.8
- ○ D. 1.2
- ○ E. 1.5

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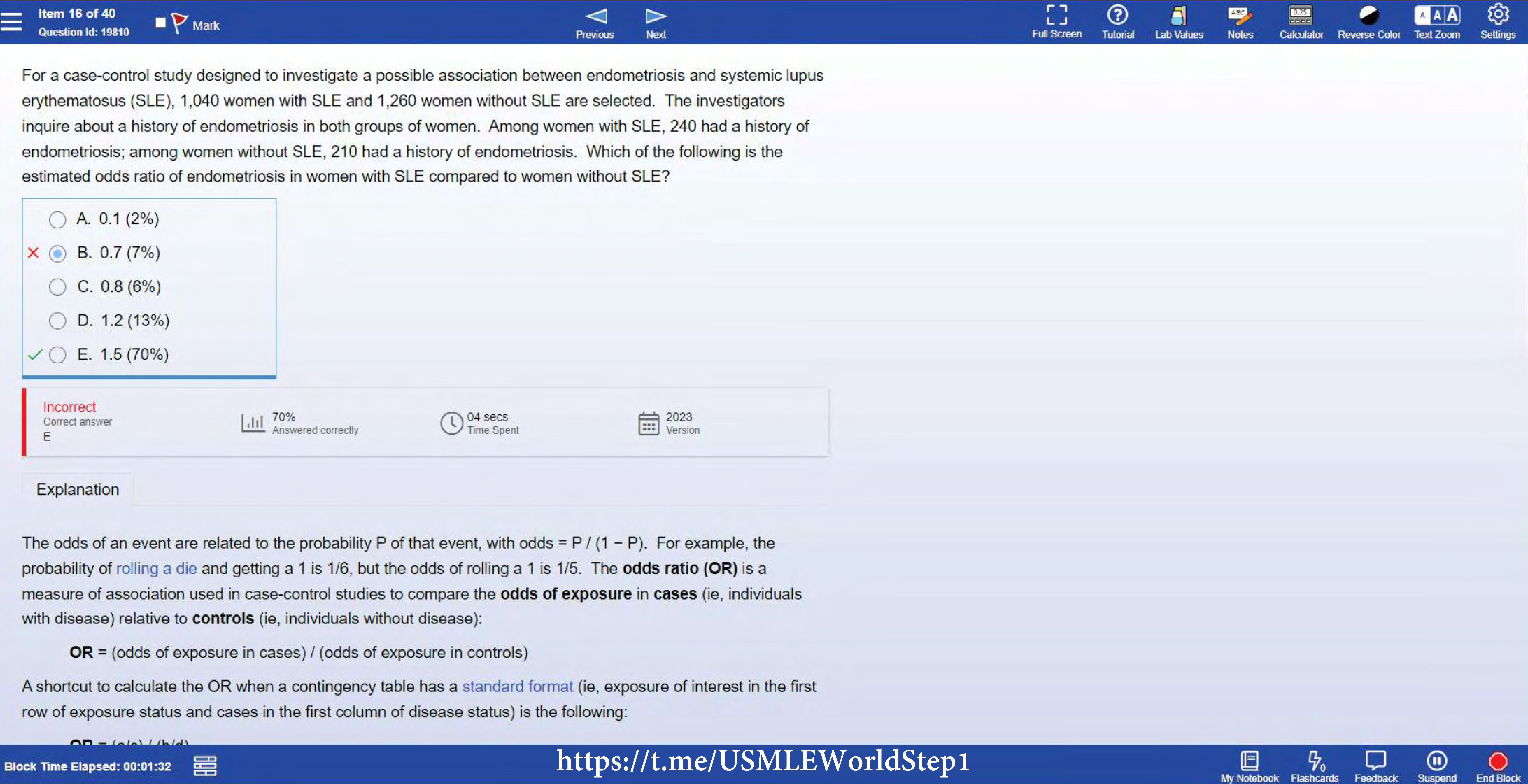
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○ A. 0.1 (2%)
✗ ● B. 0.7 (7%)
○ C. 0.8 (6%)
○ D. 1.2 (13%)
✓ ○ E. 1.5 (70%)

Incorrect
Correct answer
E

70%
Answered correctly

04 secs
Time Spent

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Version

Explanation

The odds of an event are related to the probability P of that event, with odds = P / (1 − P). For example, the probability of rolling a die and getting a 1 is 1/6, but the odds of rolling a 1 is 1/5. The **odds ratio (OR)** is a measure of association used in case-control studies to compare the **odds of exposure** in **cases** (ie, individuals with disease) relative to **controls** (ie, individuals without disease):

OR = (odds of exposure in cases) / (odds of exposure in controls)

A shortcut to calculate the OR when a contingency table has a standard format (ie, exposure of interest in the first row of exposure status and cases in the first column of disease status) is the following:

OR = (a/c) / (b/d)

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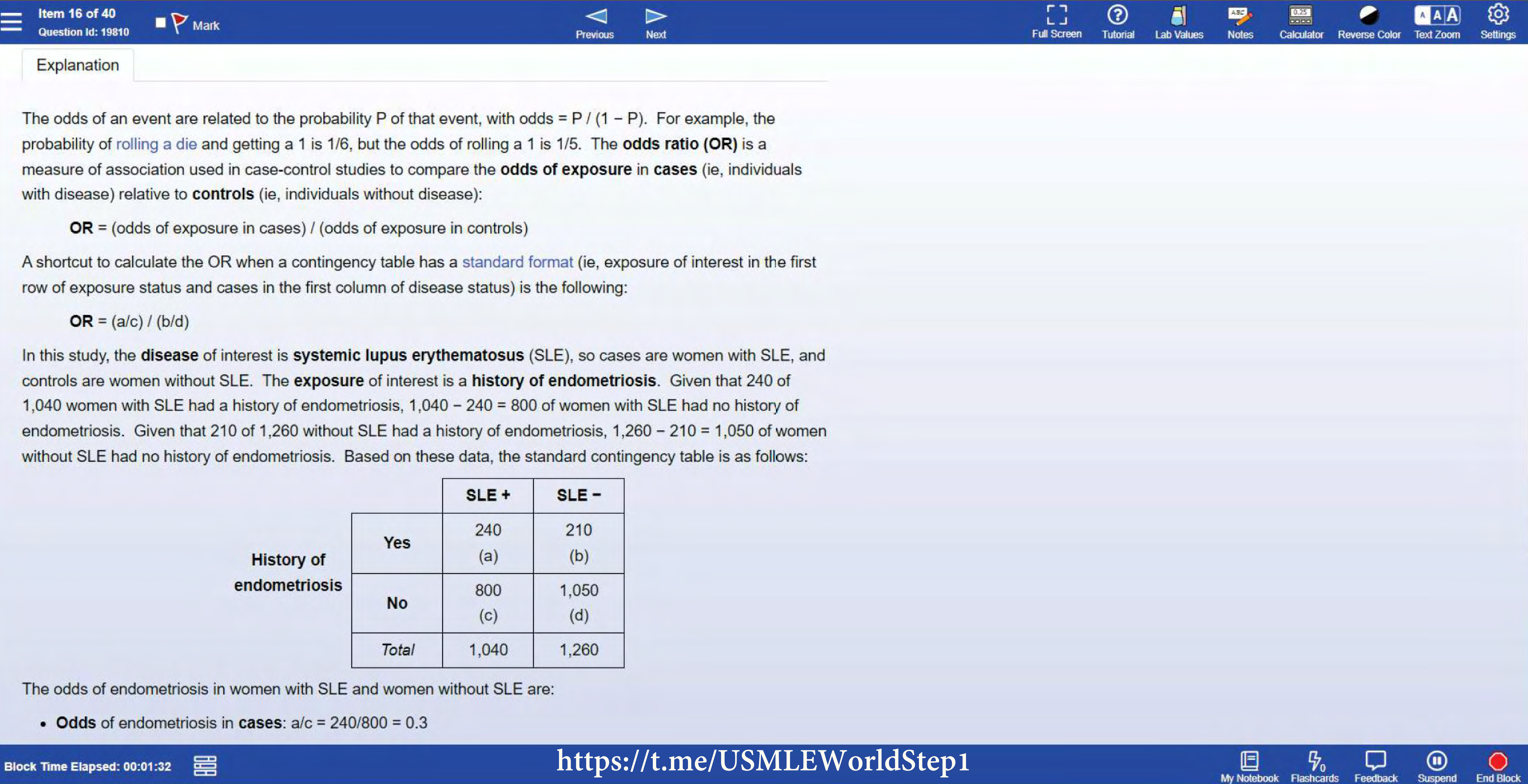

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Explanation

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OR = (odds of exposure in cases) / (odds of exposure in controls)

A shortcut to calculate the OR when a contingency table has a standard format (ie, exposure of interest in the first row of exposure status and cases in the first column of disease status) is the following:

OR = (a/c) / (b/d)

In this study, the **disease** of interest is **systemic lupus erythematosus** (SLE), so cases are women with SLE, and controls are women without SLE. The **exposure** of interest is a **history of endometriosis**. Given that 240 of 1,040 women with SLE had a history of endometriosis, 1,040 − 240 = 800 of women with SLE had no history of endometriosis. Given that 210 of 1,260 without SLE had a history of endometriosis, 1,260 − 210 = 1,050 of women without SLE had no history of endometriosis. Based on these data, the standard contingency table is as follows:

		SLE +	**SLE −**
History of endometriosis	**Yes**	240 (a)	210 (b)
	No	800 (c)	1,050 (d)
	Total	1,040	1,260

The odds of endometriosis in women with SLE and women without SLE are:

- **Odds** of endometriosis in **cases**: a/c = 240/800 = 0.3

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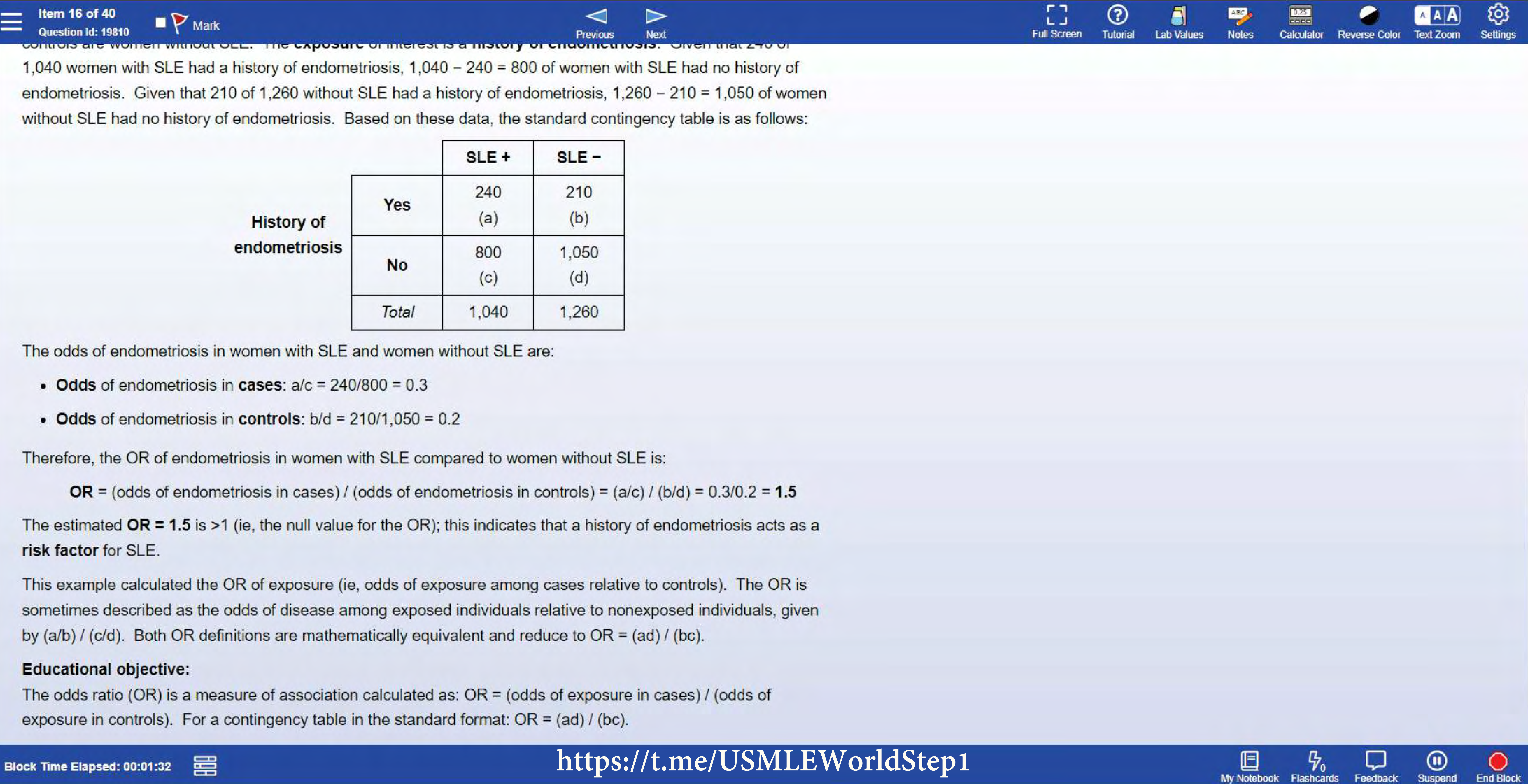
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		SLE +	**SLE −**
History of endometriosis	**Yes**	240 (a)	210 (b)
	No	800 (c)	1,050 (d)
	Total	1,040	1,260

The odds of endometriosis in women with SLE and women without SLE are:

- **Odds** of endometriosis in **cases**: a/c = 240/800 = 0.3
- **Odds** of endometriosis in **controls**: b/d = 210/1,050 = 0.2

Therefore, the OR of endometriosis in women with SLE compared to women without SLE is:

OR = (odds of endometriosis in cases) / (odds of endometriosis in controls) = (a/c) / (b/d) = 0.3/0.2 = **1.5**

The estimated **OR = 1.5** is >1 (ie, the null value for the OR); this indicates that a history of endometriosis acts as a **risk factor** for SLE.

This example calculated the OR of exposure (ie, odds of exposure among cases relative to controls). The OR is sometimes described as the odds of disease among exposed individuals relative to nonexposed individuals, given by (a/b) / (c/d). Both OR definitions are mathematically equivalent and reduce to OR = (ad) / (bc).

Educational objective:

The odds ratio (OR) is a measure of association calculated as: OR = (odds of exposure in cases) / (odds of exposure in controls). For a contingency table in the standard format: OR = (ad) / (bc).

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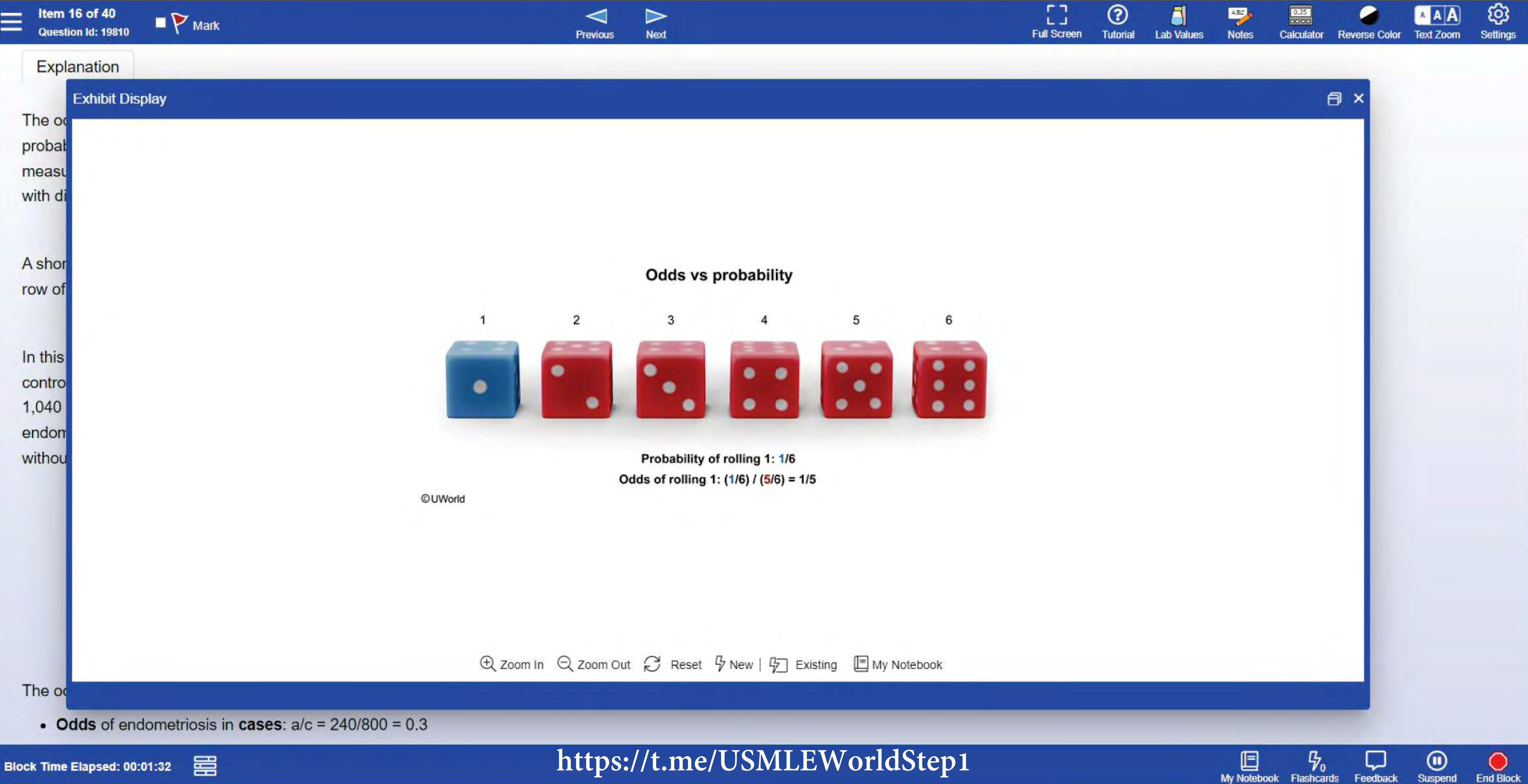
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Odds vs probability

Probability of rolling 1: 1/6

Odds of rolling 1: (1/6) / (5/6) = 1/5

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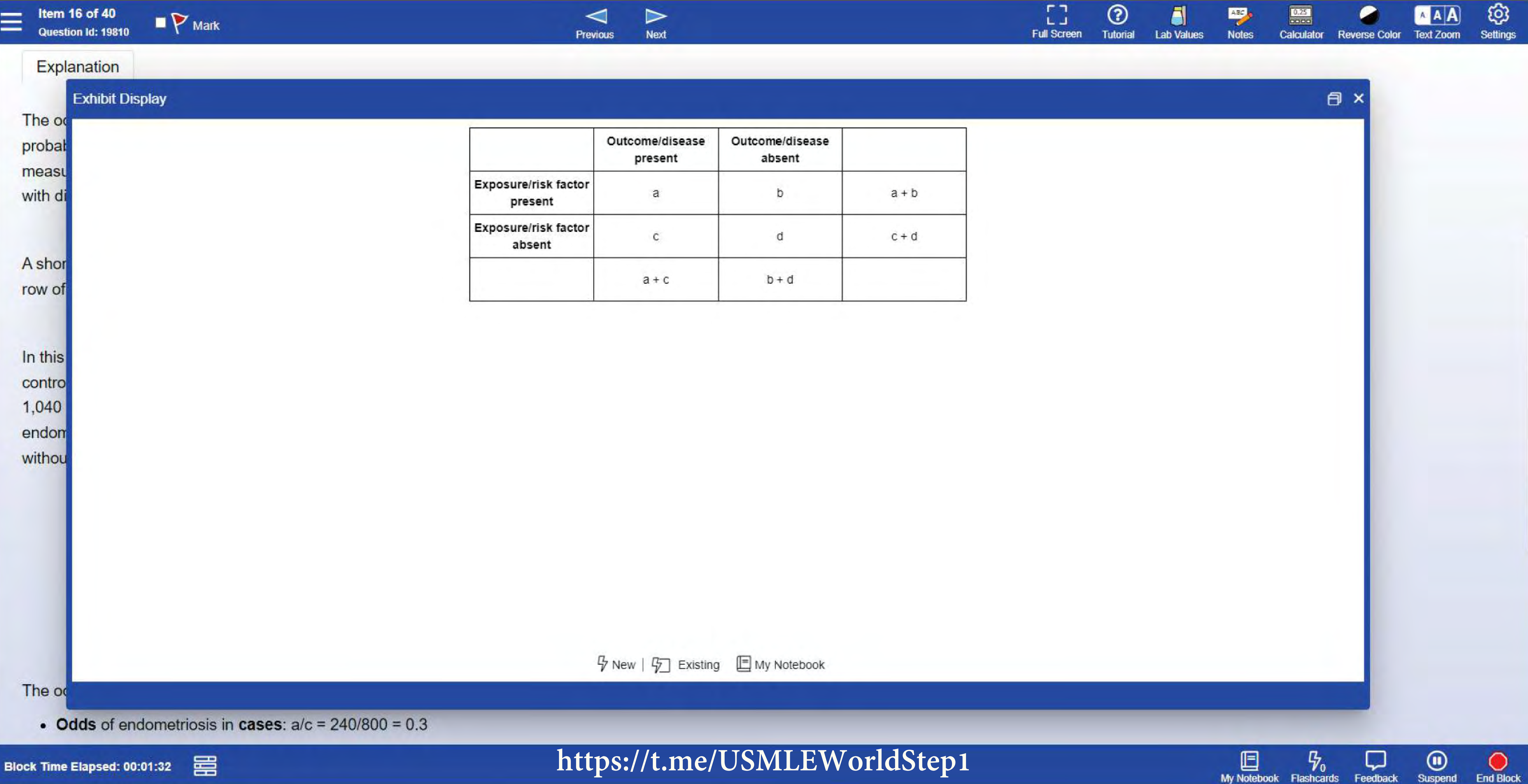
- **Odds** of endometriosis in **cases**: a/c = 240/800 = 0.3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	Outcome/disease present	Outcome/disease absent	
Exposure/risk factor present	a	b	a + b
Exposure/risk factor absent	c	d	c + d
	a + c	b + d	

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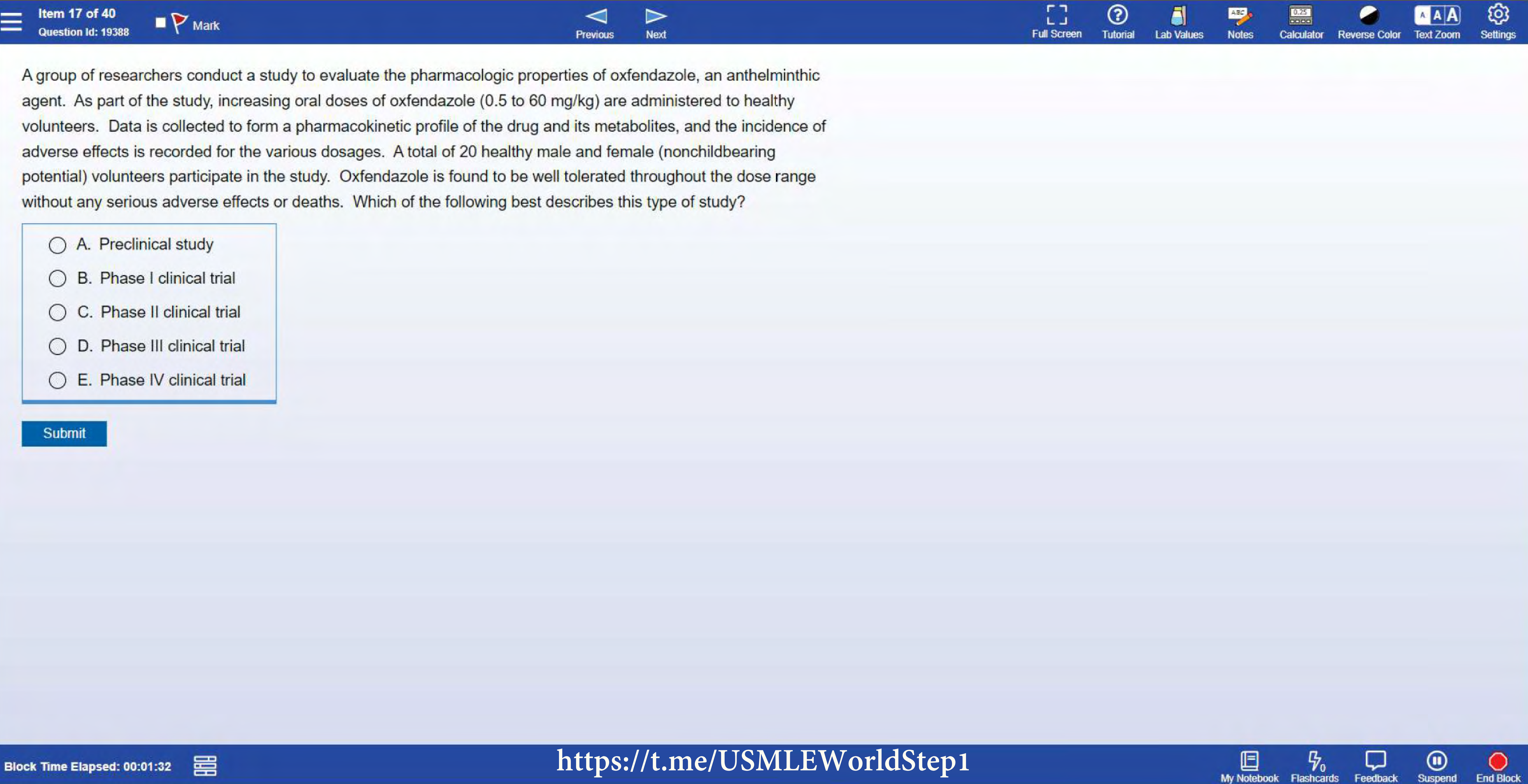
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A group of researchers conduct a study to evaluate the pharmacologic properties of oxfendazole, an anthelminthic agent. As part of the study, increasing oral doses of oxfendazole (0.5 to 60 mg/kg) are administered to healthy volunteers. Data is collected to form a pharmacokinetic profile of the drug and its metabolites, and the incidence of adverse effects is recorded for the various dosages. A total of 20 healthy male and female (nonchildbearing potential) volunteers participate in the study. Oxfendazole is found to be well tolerated throughout the dose range without any serious adverse effects or deaths. Which of the following best describes this type of study?

○ A. Preclinical study
○ B. Phase I clinical trial
○ C. Phase II clinical trial
○ D. Phase III clinical trial
○ E. Phase IV clinical trial

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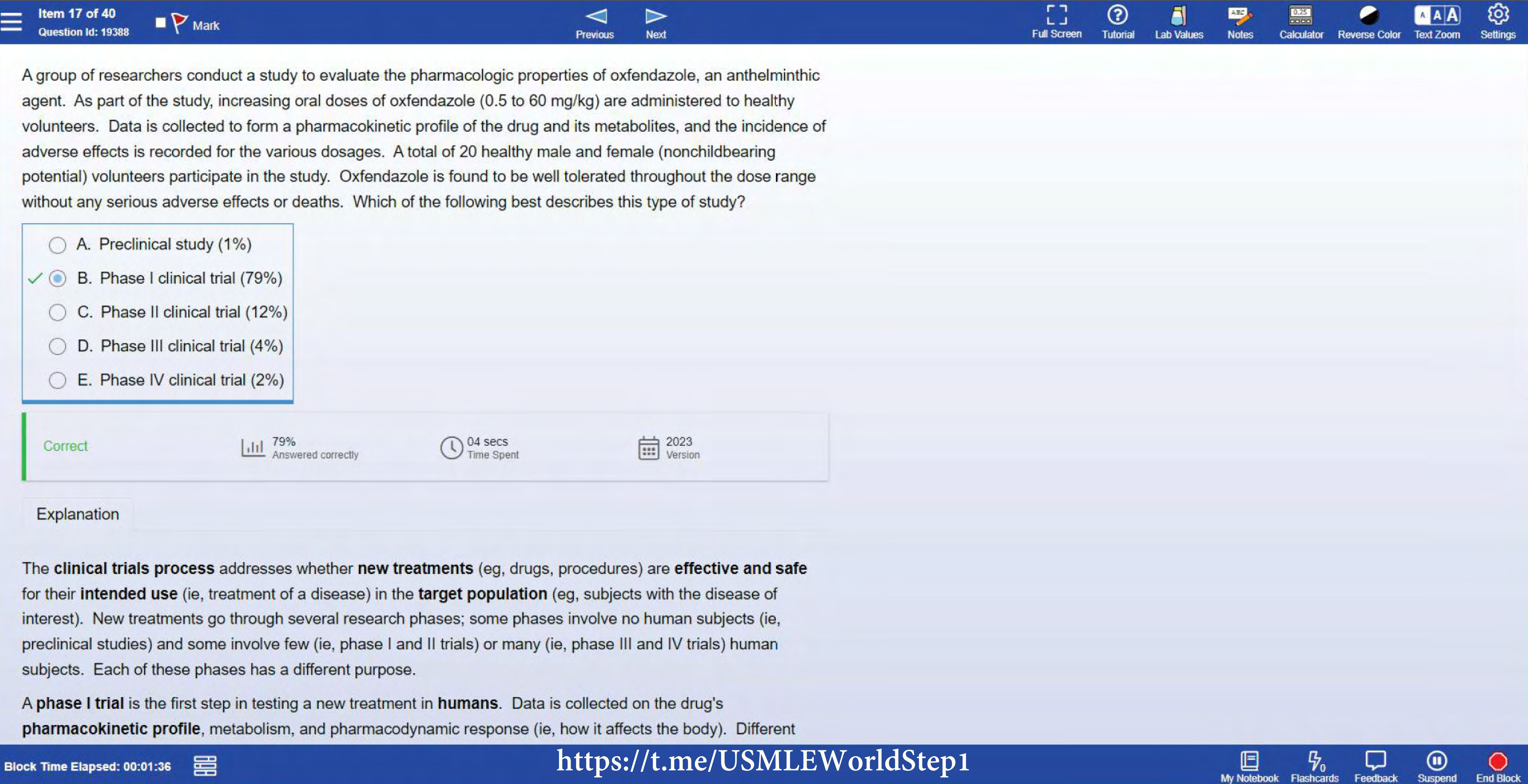
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○ A. Preclinical study (1%)
✓ ● B. Phase I clinical trial (79%)
○ C. Phase II clinical trial (12%)
○ D. Phase III clinical trial (4%)
○ E. Phase IV clinical trial (2%)

Correct
79% Answered correctly
04 secs Time Spent
2023 Version

Explanation

The **clinical trials process** addresses whether **new treatments** (eg, drugs, procedures) are **effective and safe** for their **intended use** (ie, treatment of a disease) in the **target population** (eg, subjects with the disease of interest). New treatments go through several research phases; some phases involve no human subjects (ie, preclinical studies) and some involve few (ie, phase I and II trials) or many (ie, phase III and IV trials) human subjects. Each of these phases has a different purpose.

A **phase I trial** is the first step in testing a new treatment in **humans**. Data is collected on the drug's **pharmacokinetic profile**, metabolism, and pharmacodynamic response (ie, how it affects the body). Different

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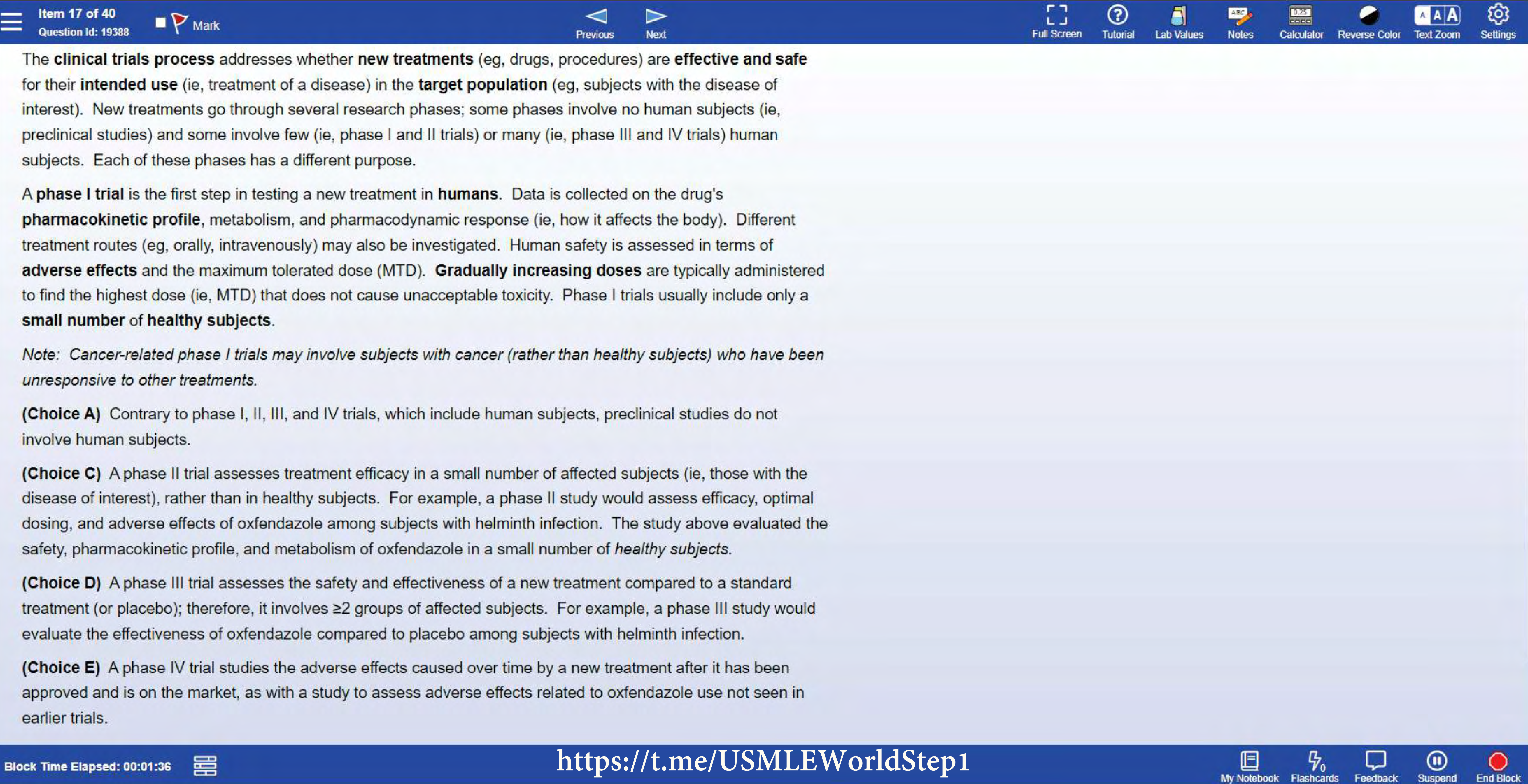

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A **phase I trial** is the first step in testing a new treatment in **humans**. Data is collected on the drug's **pharmacokinetic profile**, metabolism, and pharmacodynamic response (ie, how it affects the body). Different treatment routes (eg, orally, intravenously) may also be investigated. Human safety is assessed in terms of **adverse effects** and the maximum tolerated dose (MTD). **Gradually increasing doses** are typically administered to find the highest dose (ie, MTD) that does not cause unacceptable toxicity. Phase I trials usually include only a **small number** of **healthy subjects**.

Note: Cancer-related phase I trials may involve subjects with cancer (rather than healthy subjects) who have been unresponsive to other treatments.

(Choice A) Contrary to phase I, II, III, and IV trials, which include human subjects, preclinical studies do not involve human subjects.

(Choice C) A phase II trial assesses treatment efficacy in a small number of affected subjects (ie, those with the disease of interest), rather than in healthy subjects. For example, a phase II study would assess efficacy, optimal dosing, and adverse effects of oxfendazole among subjects with helminth infection. The study above evaluated the safety, pharmacokinetic profile, and metabolism of oxfendazole in a small number of *healthy subjects*.

(Choice D) A phase III trial assesses the safety and effectiveness of a new treatment compared to a standard treatment (or placebo); therefore, it involves ≥2 groups of affected subjects. For example, a phase III study would evaluate the effectiveness of oxfendazole compared to placebo among subjects with helminth infection.

(Choice E) A phase IV trial studies the adverse effects caused over time by a new treatment after it has been approved and is on the market, as with a study to assess adverse effects related to oxfendazole use not seen in earlier trials.

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(Choice E) A phase IV trial studies the adverse effects caused over time by a new treatment after it has been approved and is on the market, as with a study to assess adverse effects related to oxfendazole use not seen in earlier trials.

Educational objective:

A phase I trial assesses the pharmacokinetics, pharmacodynamics, and safety profile (eg, adverse events, toxicity) of a new treatment in humans. It is usually conducted on a small number of healthy subjects.

Biostatistics	Biostatistics & Epidemiology	Clinical trials
Subject	System	Topic

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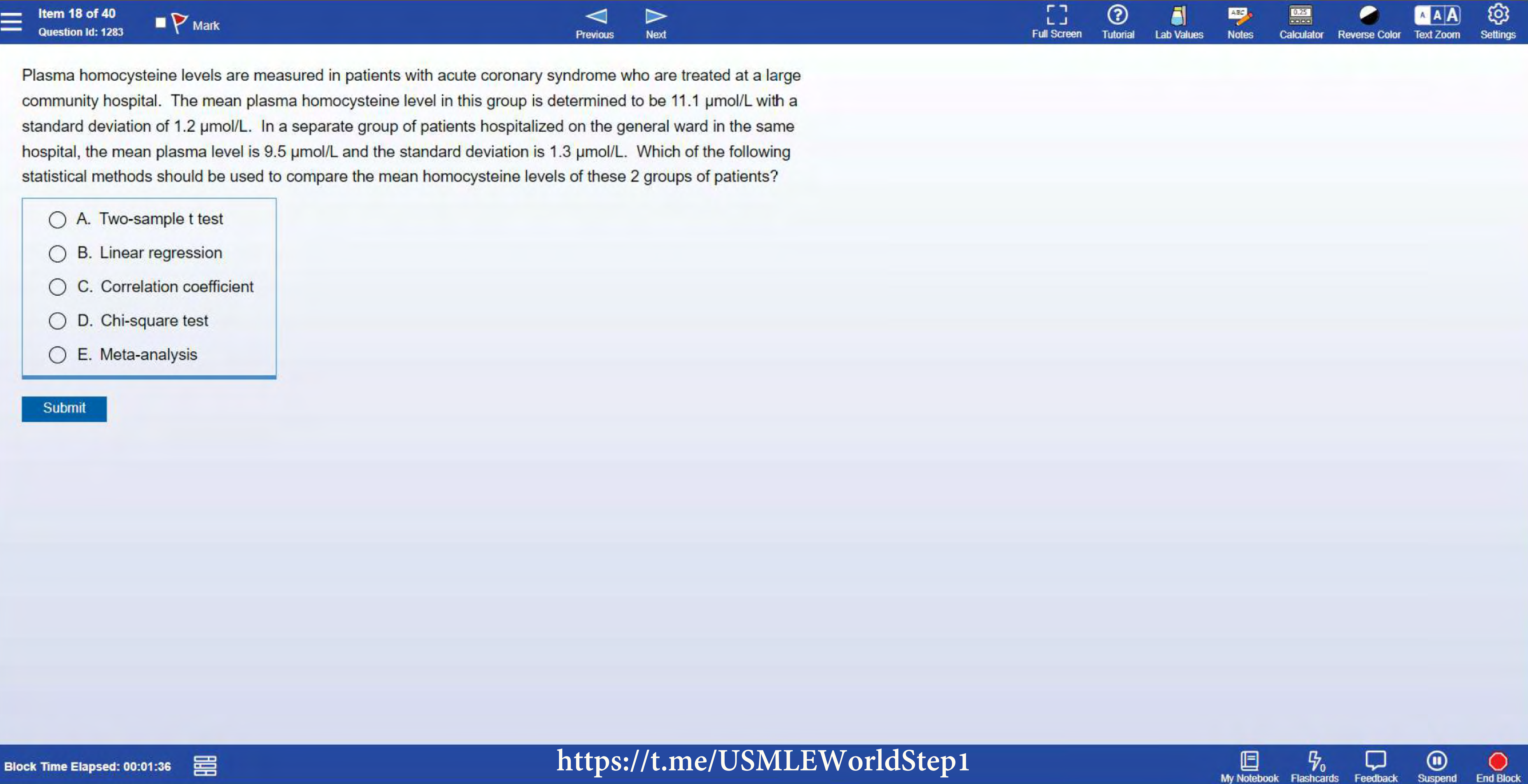
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Plasma homocysteine levels are measured in patients with acute coronary syndrome who are treated at a large community hospital. The mean plasma homocysteine level in this group is determined to be 11.1 µmol/L with a standard deviation of 1.2 µmol/L. In a separate group of patients hospitalized on the general ward in the same hospital, the mean plasma level is 9.5 µmol/L and the standard deviation is 1.3 µmol/L. Which of the following statistical methods should be used to compare the mean homocysteine levels of these 2 groups of patients?

○ A. Two-sample t test
○ B. Linear regression
○ C. Correlation coefficient
○ D. Chi-square test
○ E. Meta-analysis

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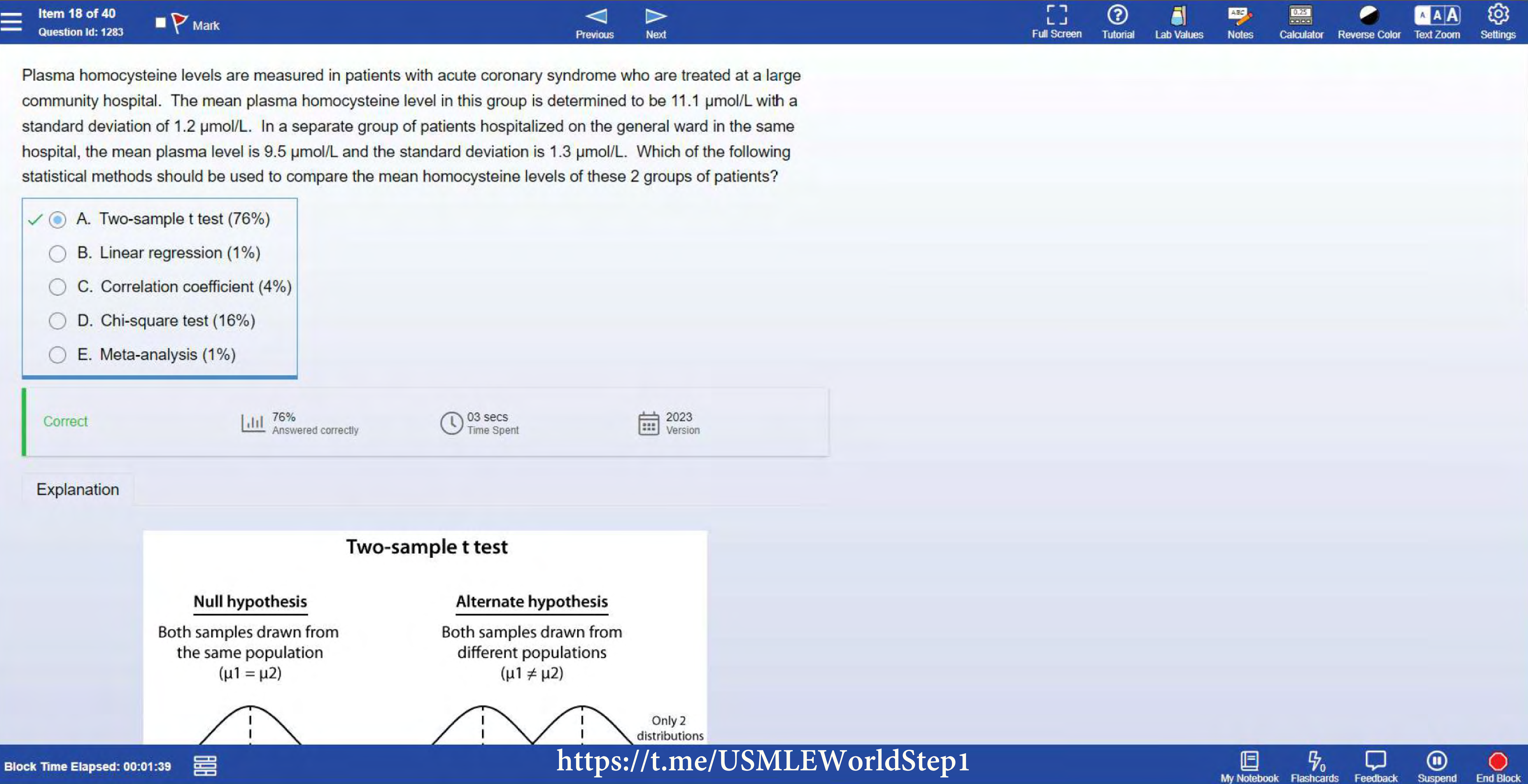
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- ✓ ● A. Two-sample t test (76%)
- ○ B. Linear regression (1%)
- ○ C. Correlation coefficient (4%)
- ○ D. Chi-square test (16%)
- ○ E. Meta-analysis (1%)

Correct | 76% Answered correctly | 03 secs Time Spent | 2023 Version

Explanation

Two-sample t test

Null hypothesis
Both samples drawn from the same population
(µ1 = µ2)
Alternate hypothesis
Both samples drawn from different populations
(µ1 ≠ µ2)
Only 2 distributions

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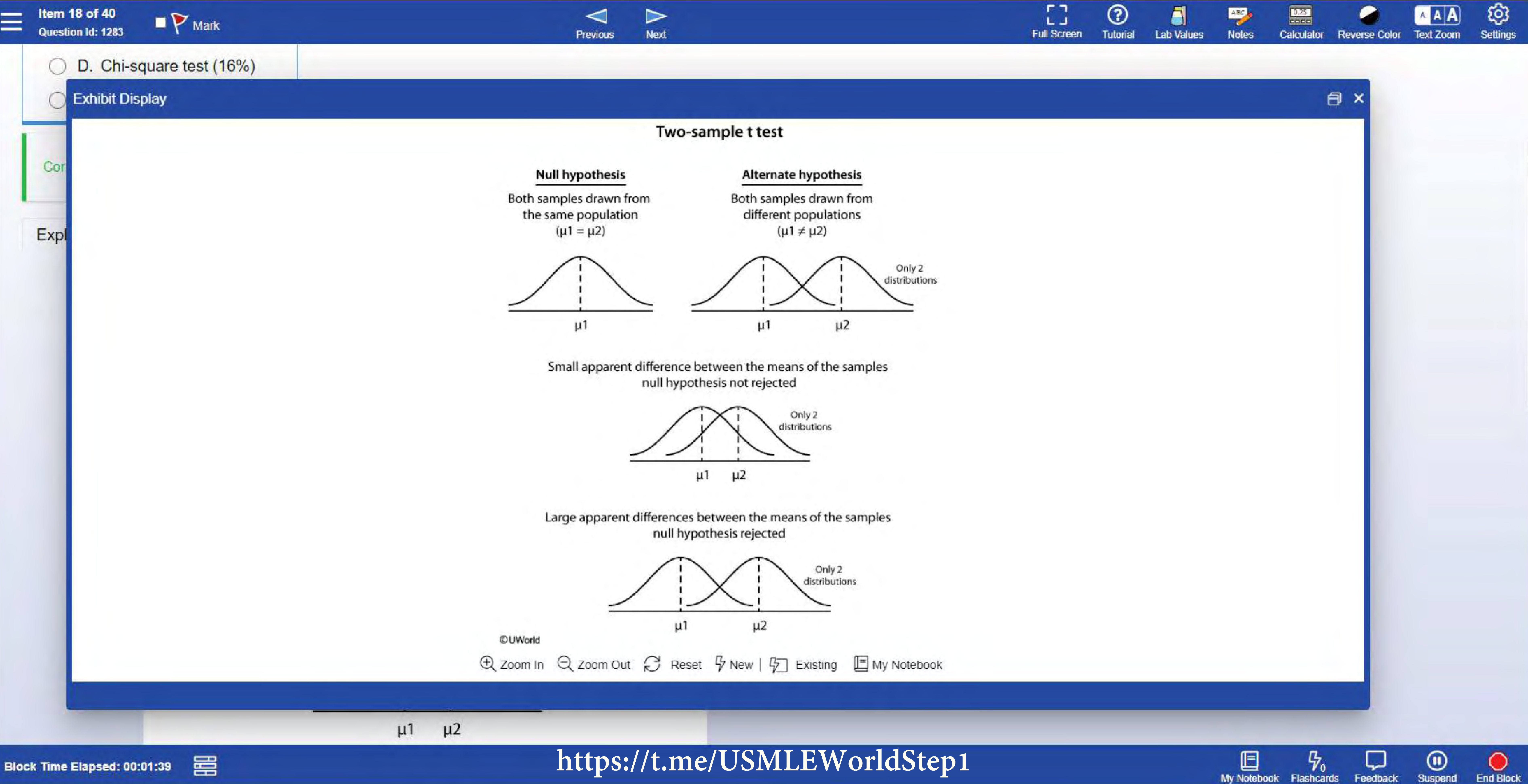
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○ D. Chi-square test (16%)

Two-sample t test

Null hypothesis

Both samples drawn from
the same population
(μ1 = μ2)

Alternate hypothesis

Both samples drawn from
different populations
(μ1 ≠ μ2)

μ1
μ1
μ2
Only 2 distributions

Small apparent difference between the means of the samples
null hypothesis not rejected

μ1
μ2
Only 2 distributions

Large apparent differences between the means of the samples
null hypothesis rejected

μ1
μ2
Only 2 distributions

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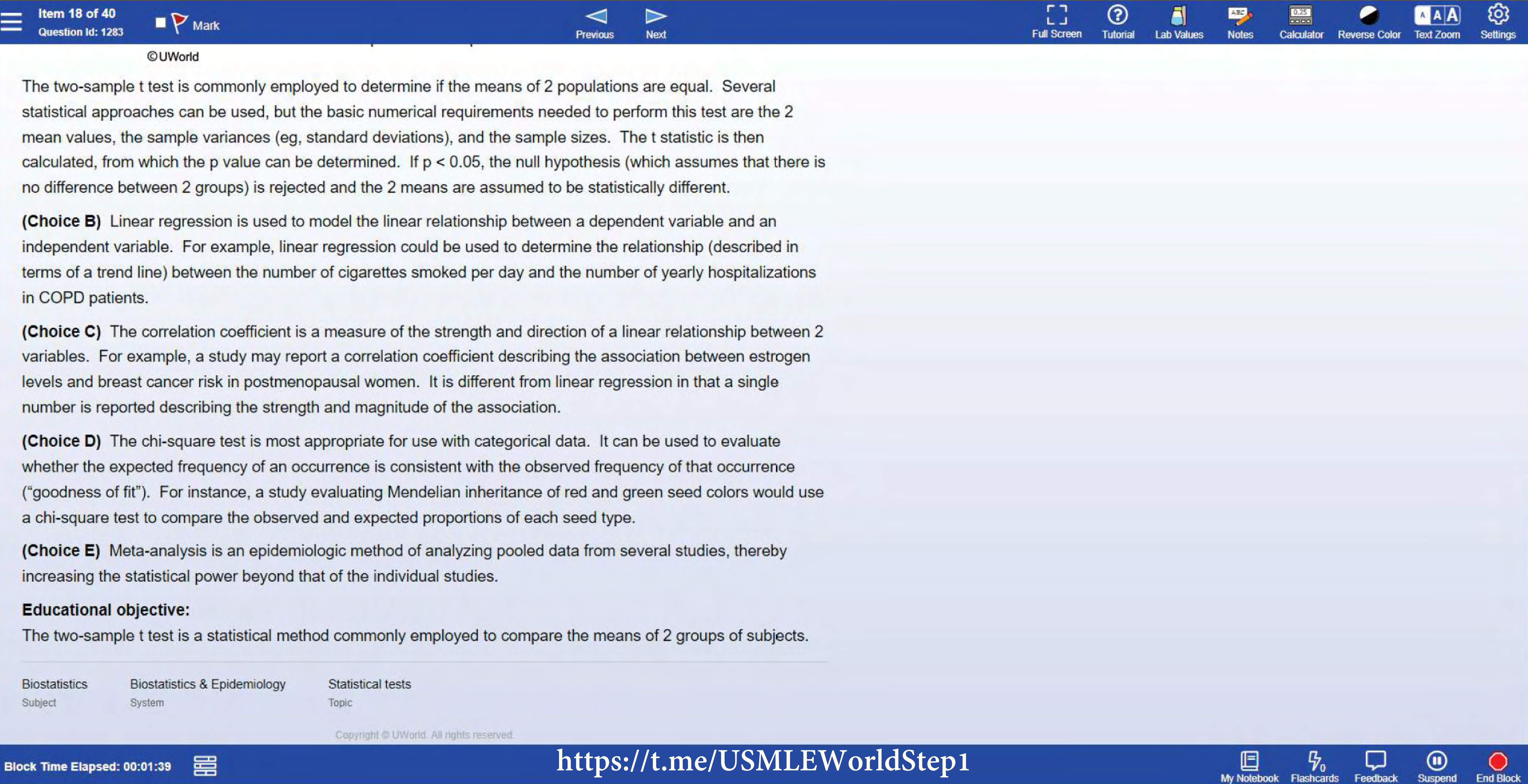

The two-sample t test is commonly employed to determine if the means of 2 populations are equal. Several statistical approaches can be used, but the basic numerical requirements needed to perform this test are the 2 mean values, the sample variances (eg, standard deviations), and the sample sizes. The t statistic is then calculated, from which the p value can be determined. If $p < 0.05$, the null hypothesis (which assumes that there is no difference between 2 groups) is rejected and the 2 means are assumed to be statistically different.

(Choice B) Linear regression is used to model the linear relationship between a dependent variable and an independent variable. For example, linear regression could be used to determine the relationship (described in terms of a trend line) between the number of cigarettes smoked per day and the number of yearly hospitalizations in COPD patients.

(Choice C) The correlation coefficient is a measure of the strength and direction of a linear relationship between 2 variables. For example, a study may report a correlation coefficient describing the association between estrogen levels and breast cancer risk in postmenopausal women. It is different from linear regression in that a single number is reported describing the strength and magnitude of the association.

(Choice D) The chi-square test is most appropriate for use with categorical data. It can be used to evaluate whether the expected frequency of an occurrence is consistent with the observed frequency of that occurrence ("goodness of fit"). For instance, a study evaluating Mendelian inheritance of red and green seed colors would use a chi-square test to compare the observed and expected proportions of each seed type.

(Choice E) Meta-analysis is an epidemiologic method of analyzing pooled data from several studies, thereby increasing the statistical power beyond that of the individual studies.

Educational objective:

The two-sample t test is a statistical method commonly employed to compare the means of 2 groups of subjects.

Biostatistics	Biostatistics & Epidemiology	Statistical tests
Subject	System	Topic

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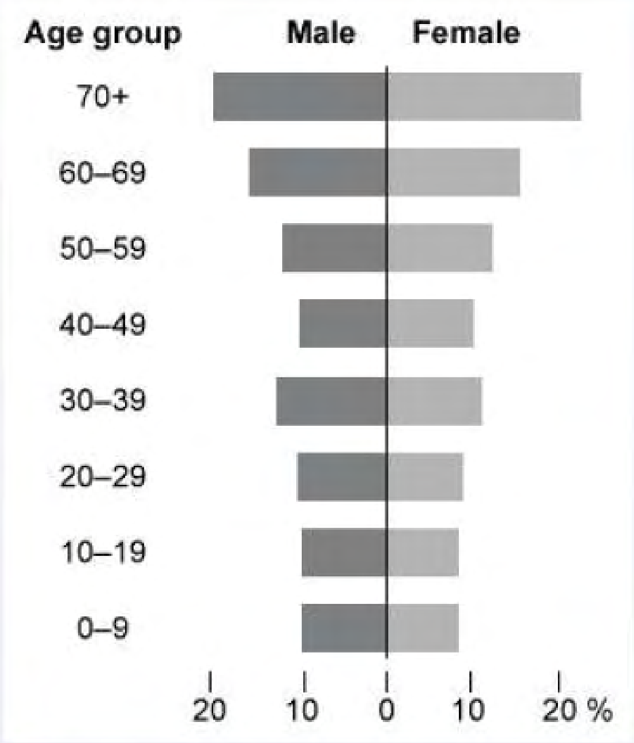
A study is conducted to describe the age-sex distribution of a certain country. According to national data, the population pyramid of the country has the shape shown below.



Based on the population pyramid, which of the following is most likely true about this country and its population?

○ A. The country seems to have high birth rates; therefore, the population must be growing

○ B. The country seems to have a high death rate; therefore, the population must be shrinking

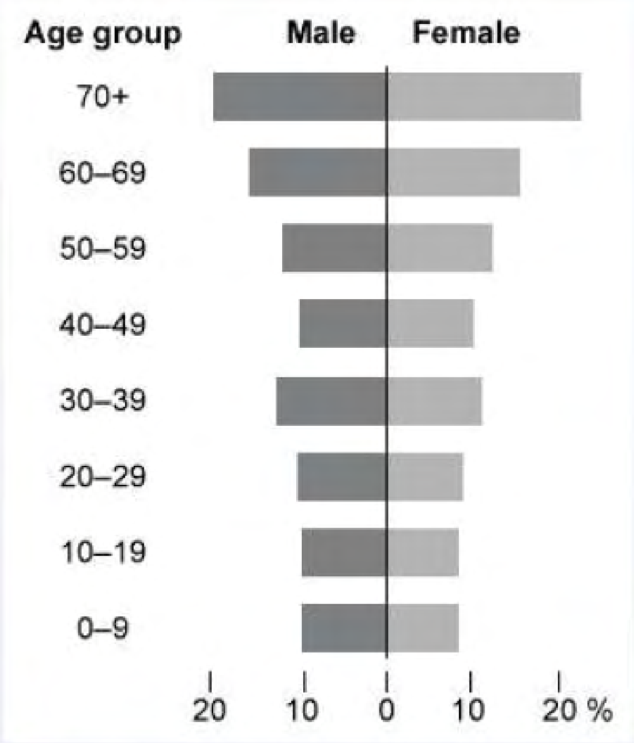
○ C. The country seems to have a low birth rate; therefore, the population must be old

○ D. The country seems to have a short life expectancy; therefore, the population must be young

○ E. The country seems to have a similar percentage of people in each age cohort; therefore, the population must be stable

Submit

A study is conducted to describe the age-sex distribution of a certain country. According to national data, the population pyramid of the country has the shape shown below.



Based on the population pyramid, which of the following is most likely true about this country and its population?

- ✗ ● A. The country seems to have high birth rates; therefore, the population must be growing (0%)
- ○ B. The country seems to have a high death rate; therefore, the population must be shrinking (1%)
- ✓ ○ C. The country seems to have a low birth rate; therefore, the population must be old (77%)
- ○ D. The country seems to have a short life expectancy; therefore, the population must be young (0%)
- ○ E. The country seems to have a similar percentage of people in each age cohort; therefore, the population must be stable (19%)

Incorrect
Correct answer
C

77%
Answered correctly

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A study is conducted to describe the age-sex distribution of a certain country. According to national data, the popula

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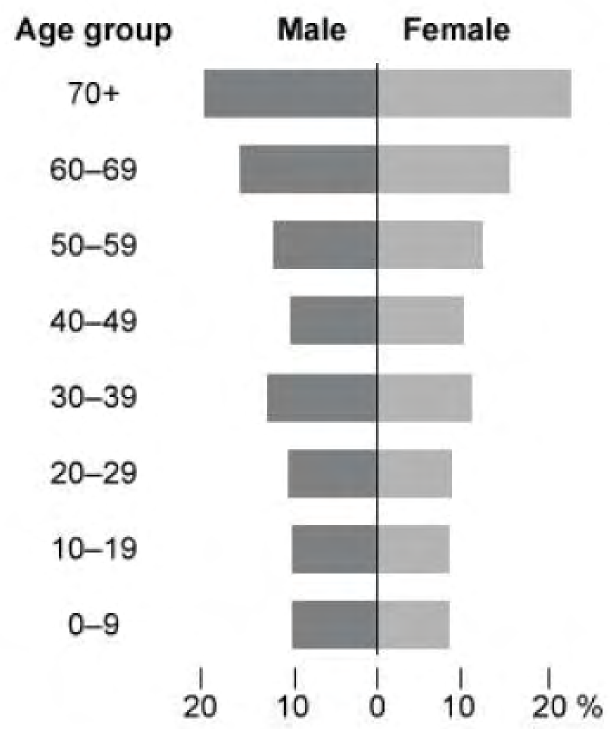

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Based

✗ ●

○

✓ ○

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Inco
Correct answer
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Answered correctly

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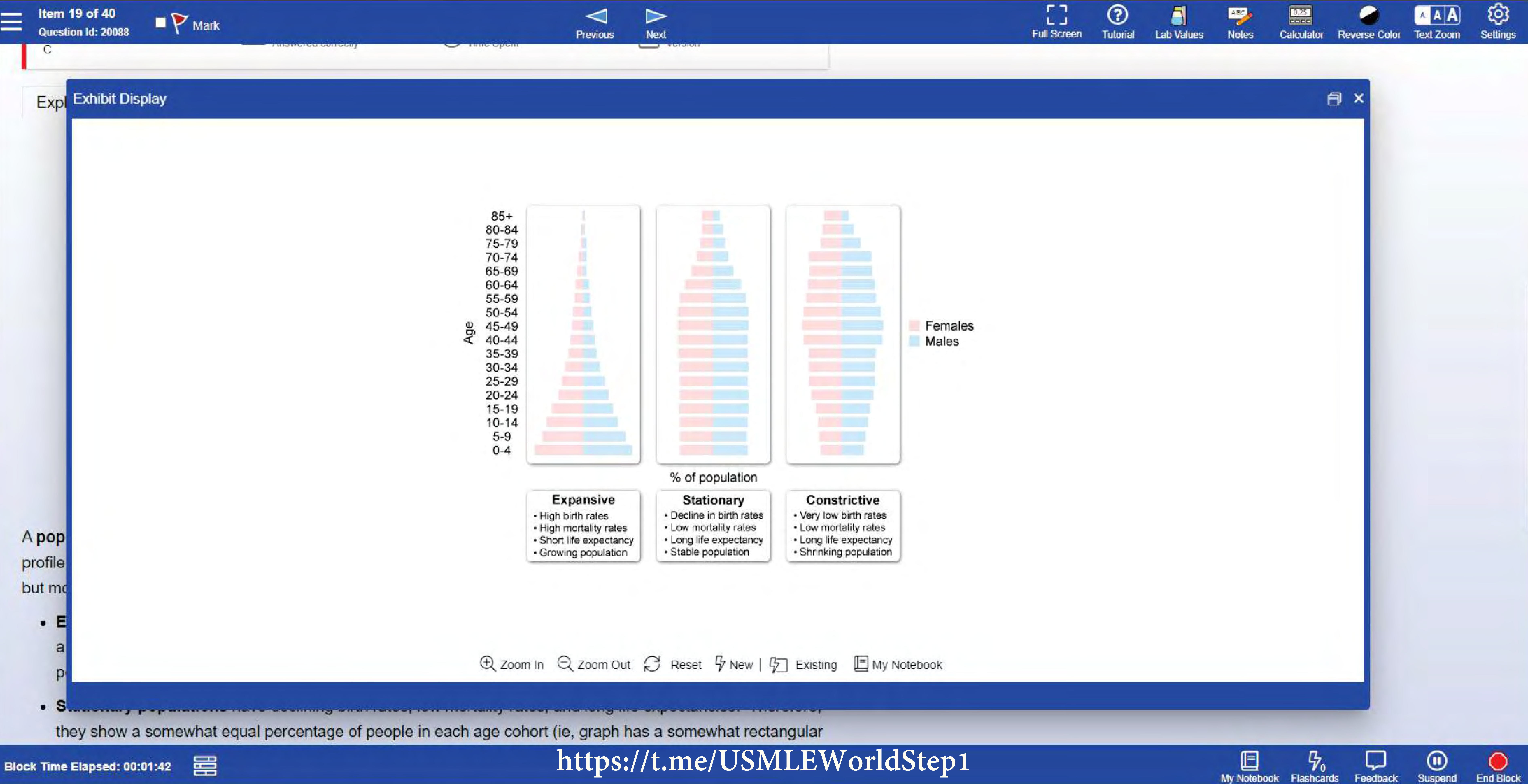
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Expansive
- High birth rates
- High mortality rates
- Short life expectancy
- Growing population

Stationary
- Decline in birth rates
- Low mortality rates
- Long life expectancy
- Stable population

Constrictive
- Very low birth rates
- Low mortality rates
- Long life expectancy
- Shrinking population

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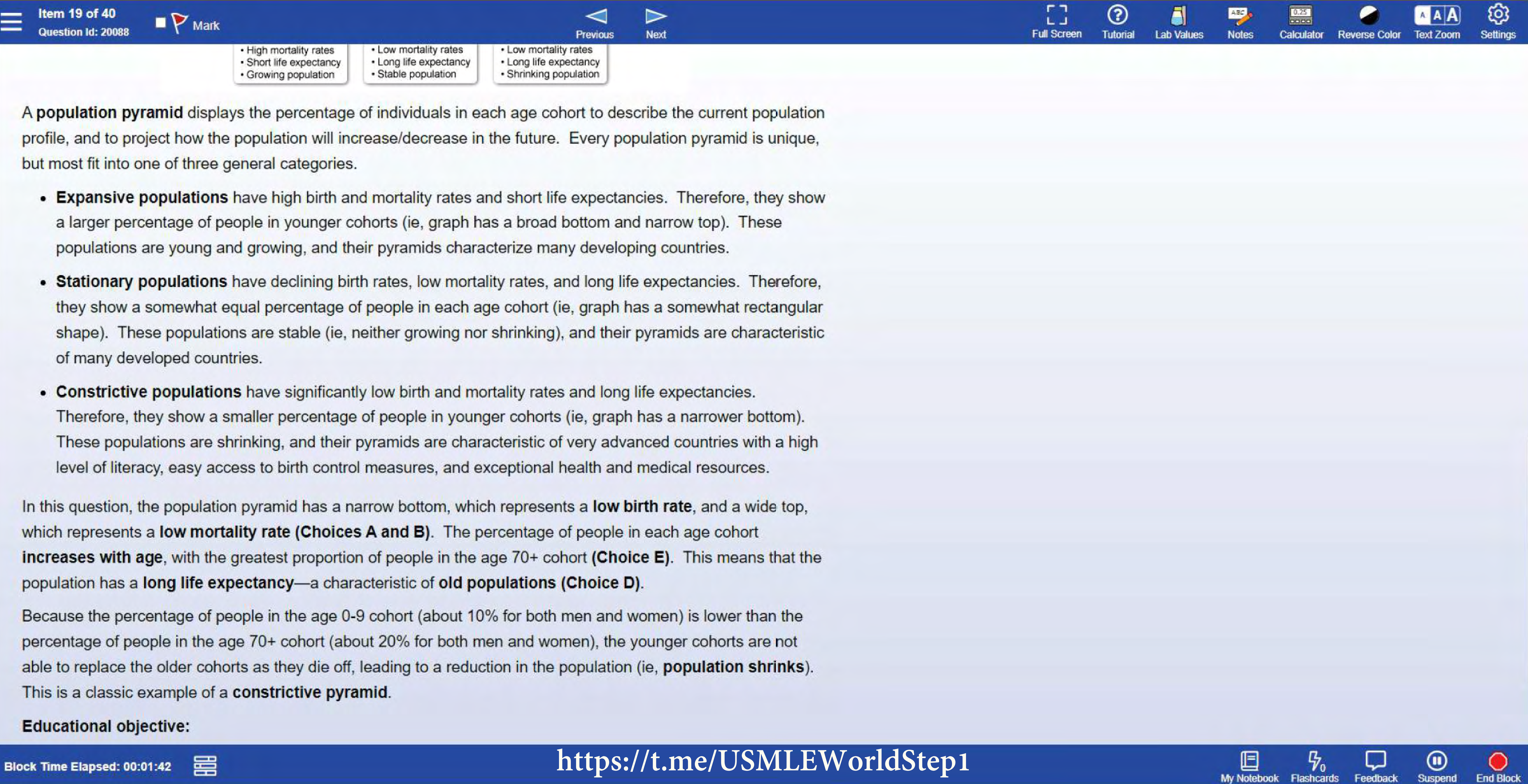
they show a somewhat equal percentage of people in each age cohort (ie, graph has a somewhat rectangular



- High mortality rates
- Short life expectancy
- Growing population

- Low mortality rates
- Long life expectancy
- Stable population

- Low mortality rates
- Long life expectancy
- Shrinking population

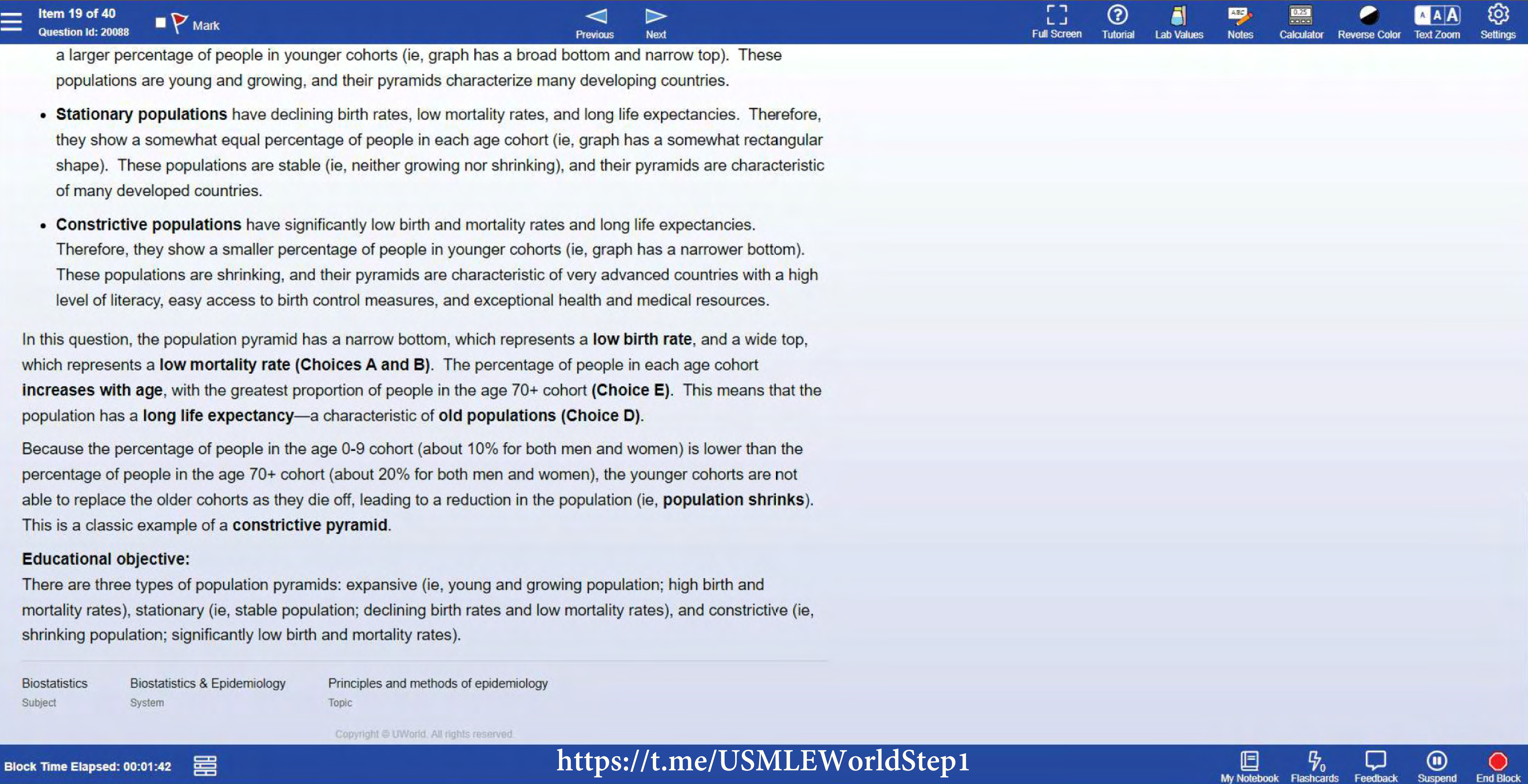
A **population pyramid** displays the percentage of individuals in each age cohort to describe the current population profile, and to project how the population will increase/decrease in the future. Every population pyramid is unique, but most fit into one of three general categories.

- **Expansive populations** have high birth and mortality rates and short life expectancies. Therefore, they show a larger percentage of people in younger cohorts (ie, graph has a broad bottom and narrow top). These populations are young and growing, and their pyramids characterize many developing countries.
- **Stationary populations** have declining birth rates, low mortality rates, and long life expectancies. Therefore, they show a somewhat equal percentage of people in each age cohort (ie, graph has a somewhat rectangular shape). These populations are stable (ie, neither growing nor shrinking), and their pyramids are characteristic of many developed countries.
- **Constrictive populations** have significantly low birth and mortality rates and long life expectancies. Therefore, they show a smaller percentage of people in younger cohorts (ie, graph has a narrower bottom). These populations are shrinking, and their pyramids are characteristic of very advanced countries with a high level of literacy, easy access to birth control measures, and exceptional health and medical resources.

In this question, the population pyramid has a narrow bottom, which represents a **low birth rate**, and a wide top, which represents a **low mortality rate (Choices A and B)**. The percentage of people in each age cohort **increases with age**, with the greatest proportion of people in the age 70+ cohort **(Choice E)**. This means that the population has a **long life expectancy**—a characteristic of **old populations (Choice D)**.

Because the percentage of people in the age 0-9 cohort (about 10% for both men and women) is lower than the percentage of people in the age 70+ cohort (about 20% for both men and women), the younger cohorts are not able to replace the older cohorts as they die off, leading to a reduction in the population (ie, **population shrinks**). This is a classic example of a **constrictive pyramid**.

Educational objective:



a larger percentage of people in younger cohorts (ie, graph has a broad bottom and narrow top). These populations are young and growing, and their pyramids characterize many developing countries.

- **Stationary populations** have declining birth rates, low mortality rates, and long life expectancies. Therefore, they show a somewhat equal percentage of people in each age cohort (ie, graph has a somewhat rectangular shape). These populations are stable (ie, neither growing nor shrinking), and their pyramids are characteristic of many developed countries.
- **Constrictive populations** have significantly low birth and mortality rates and long life expectancies. Therefore, they show a smaller percentage of people in younger cohorts (ie, graph has a narrower bottom). These populations are shrinking, and their pyramids are characteristic of very advanced countries with a high level of literacy, easy access to birth control measures, and exceptional health and medical resources.

In this question, the population pyramid has a narrow bottom, which represents a **low birth rate**, and a wide top, which represents a **low mortality rate (Choices A and B)**. The percentage of people in each age cohort **increases with age**, with the greatest proportion of people in the age 70+ cohort **(Choice E)**. This means that the population has a **long life expectancy**—a characteristic of **old populations (Choice D)**.

Because the percentage of people in the age 0-9 cohort (about 10% for both men and women) is lower than the percentage of people in the age 70+ cohort (about 20% for both men and women), the younger cohorts are not able to replace the older cohorts as they die off, leading to a reduction in the population (ie, **population shrinks**). This is a classic example of a **constrictive pyramid**.

Educational objective:
There are three types of population pyramids: expansive (ie, young and growing population; high birth and mortality rates), stationary (ie, stable population; declining birth rates and low mortality rates), and constrictive (ie, shrinking population; significantly low birth and mortality rates).

Biostatistics	Biostatistics & Epidemiology	Principles and methods of epidemiology
Subject	System	Topic

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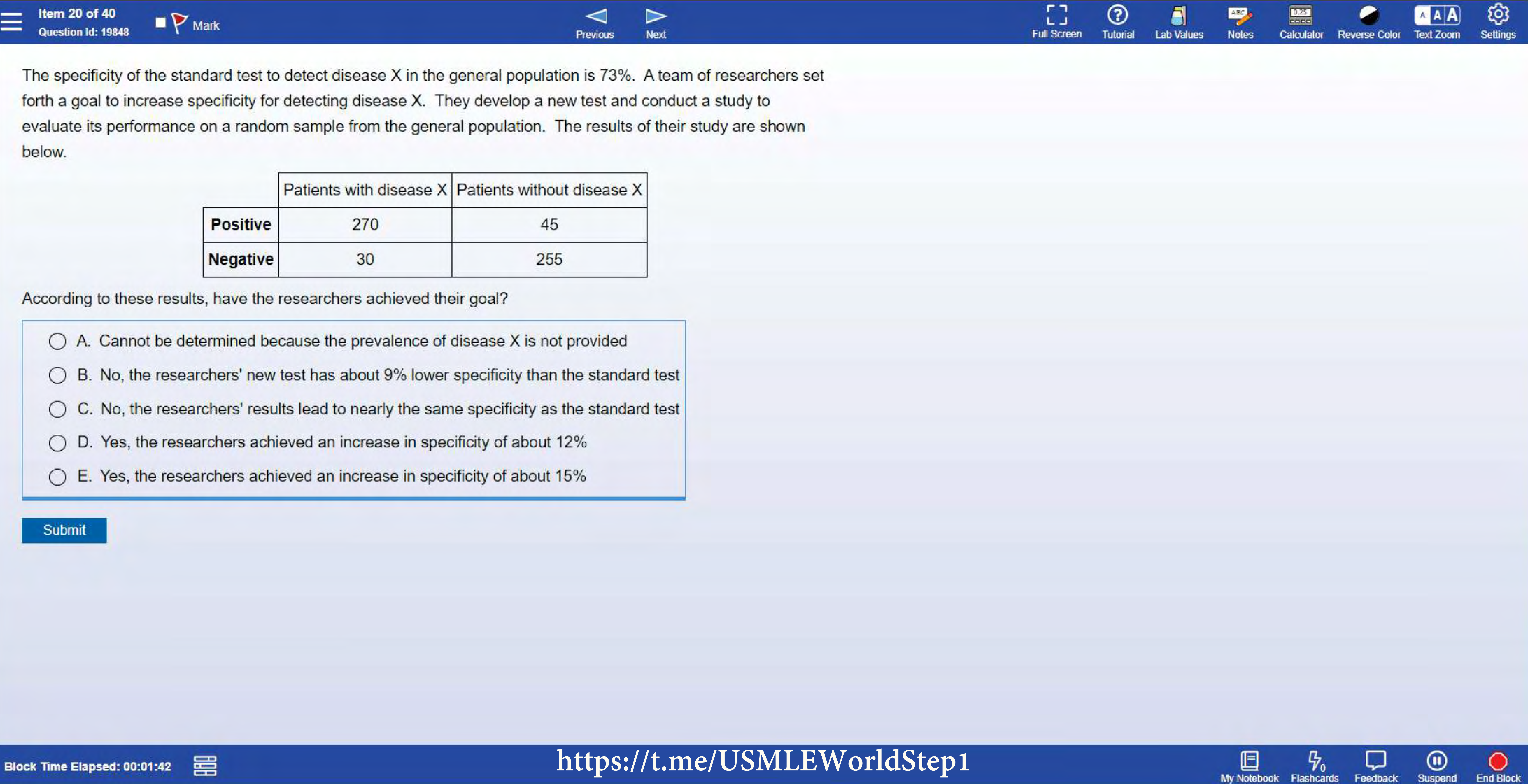
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The specificity of the standard test to detect disease X in the general population is 73%. A team of researchers set forth a goal to increase specificity for detecting disease X. They develop a new test and conduct a study to evaluate its performance on a random sample from the general population. The results of their study are shown below.

	Patients with disease X	Patients without disease X
Positive	270	45
Negative	30	255

According to these results, have the researchers achieved their goal?

○ A. Cannot be determined because the prevalence of disease X is not provided

○ B. No, the researchers' new test has about 9% lower specificity than the standard test

○ C. No, the researchers' results lead to nearly the same specificity as the standard test

○ D. Yes, the researchers achieved an increase in specificity of about 12%

○ E. Yes, the researchers achieved an increase in specificity of about 15%

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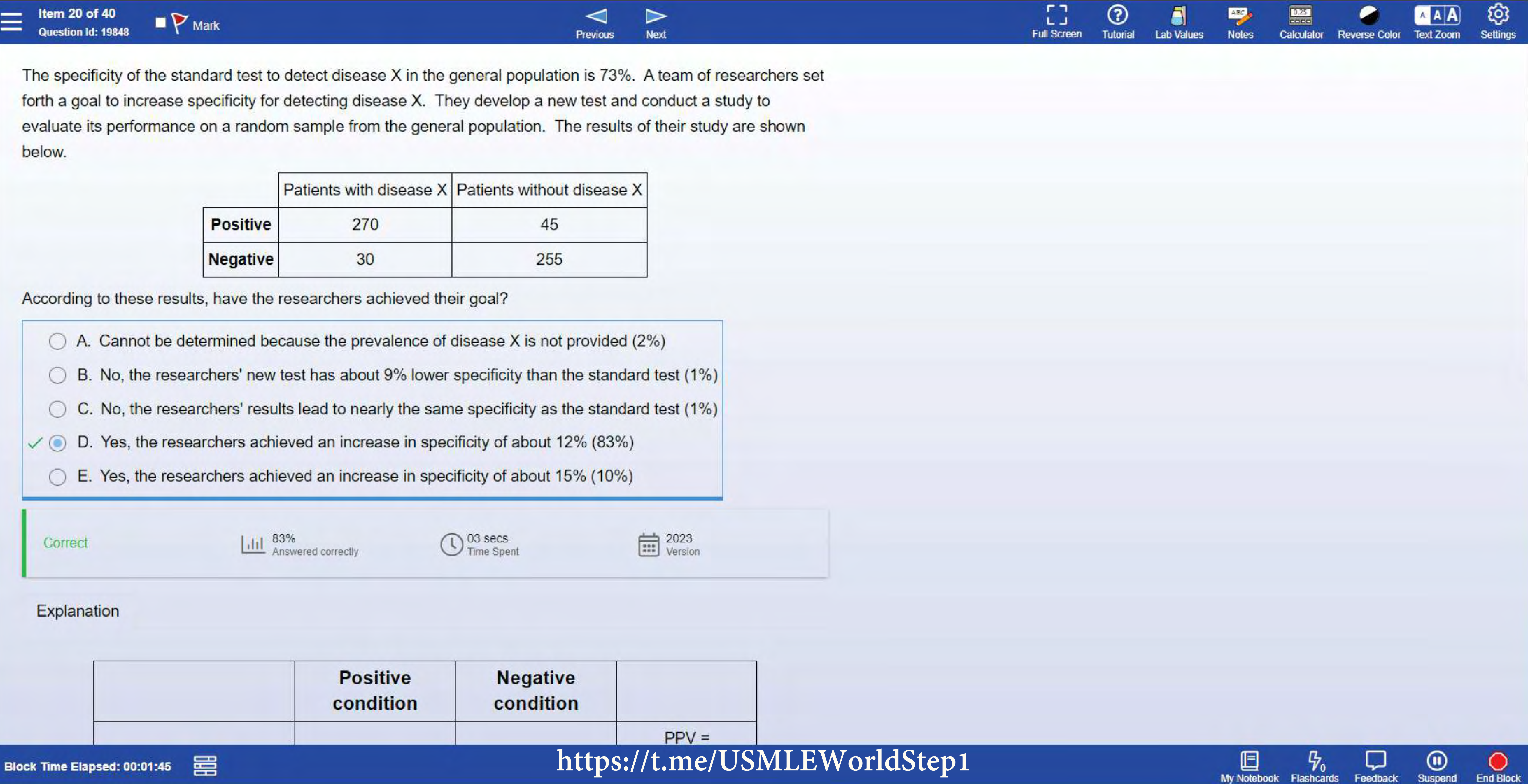
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	Patients with disease X	Patients without disease X
Positive	270	45
Negative	30	255

According to these results, have the researchers achieved their goal?

○ A. Cannot be determined because the prevalence of disease X is not provided (2%)
○ B. No, the researchers' new test has about 9% lower specificity than the standard test (1%)
○ C. No, the researchers' results lead to nearly the same specificity as the standard test (1%)
✓ ● D. Yes, the researchers achieved an increase in specificity of about 12% (83%)
○ E. Yes, the researchers achieved an increase in specificity of about 15% (10%)

Correct

83%
Answered correctly

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Explanation

	Positive condition	**Negative condition**	
			PPV =

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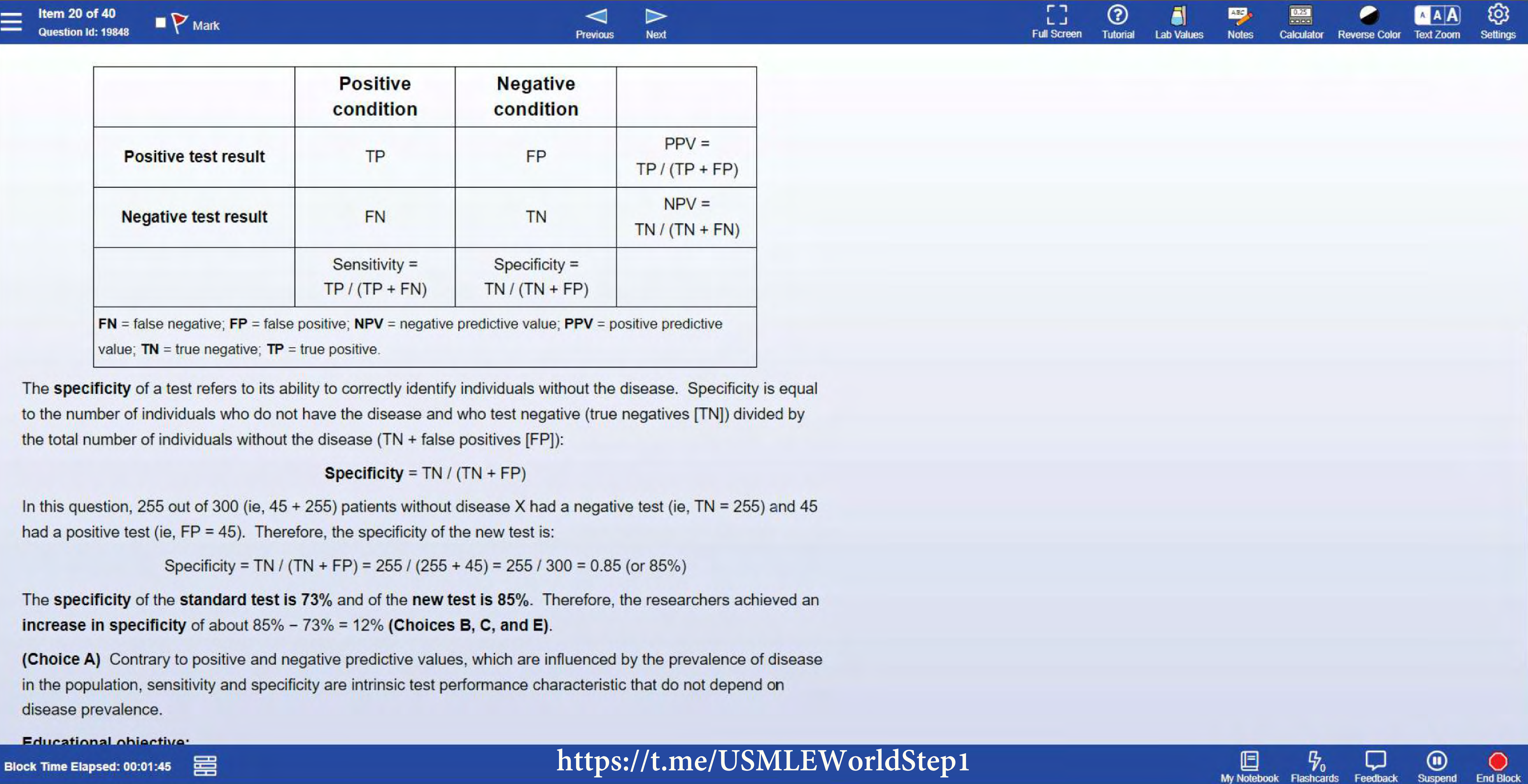
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	Positive condition	**Negative condition**	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

The **specificity** of a test refers to its ability to correctly identify individuals without the disease. Specificity is equal to the number of individuals who do not have the disease and who test negative (true negatives [TN]) divided by the total number of individuals without the disease (TN + false positives [FP]):

Specificity = TN / (TN + FP)

In this question, 255 out of 300 (ie, 45 + 255) patients without disease X had a negative test (ie, TN = 255) and 45 had a positive test (ie, FP = 45). Therefore, the specificity of the new test is:

Specificity = TN / (TN + FP) = 255 / (255 + 45) = 255 / 300 = 0.85 (or 85%)

The **specificity** of the **standard test is 73%** and of the **new test is 85%**. Therefore, the researchers achieved an **increase in specificity** of about 85% − 73% = 12% **(Choices B, C, and E)**.

(Choice A) Contrary to positive and negative predictive values, which are influenced by the prevalence of disease in the population, sensitivity and specificity are intrinsic test performance characteristic that do not depend on disease prevalence.

Educational objective:

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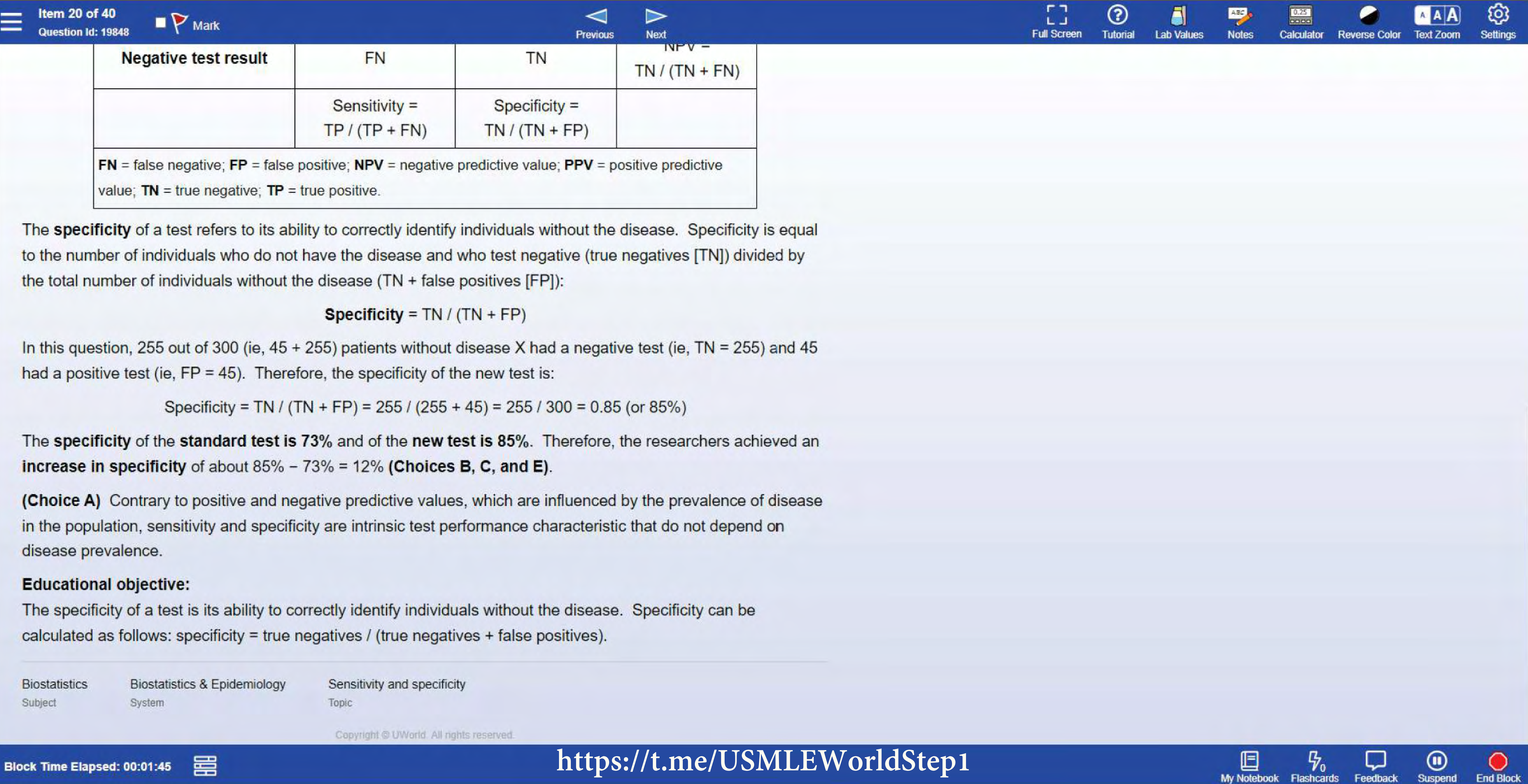
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Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

The **specificity** of a test refers to its ability to correctly identify individuals without the disease. Specificity is equal to the number of individuals who do not have the disease and who test negative (true negatives [TN]) divided by the total number of individuals without the disease (TN + false positives [FP]):

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The **specificity** of the **standard test is 73%** and of the **new test is 85%**. Therefore, the researchers achieved an **increase in specificity** of about 85% − 73% = 12% **(Choices B, C, and E)**.

(Choice A) Contrary to positive and negative predictive values, which are influenced by the prevalence of disease in the population, sensitivity and specificity are intrinsic test performance characteristic that do not depend on disease prevalence.

Educational objective:
The specificity of a test is its ability to correctly identify individuals without the disease. Specificity can be calculated as follows: specificity = true negatives / (true negatives + false positives).

Biostatistics	Biostatistics & Epidemiology	Sensitivity and specificity
Subject	System	Topic

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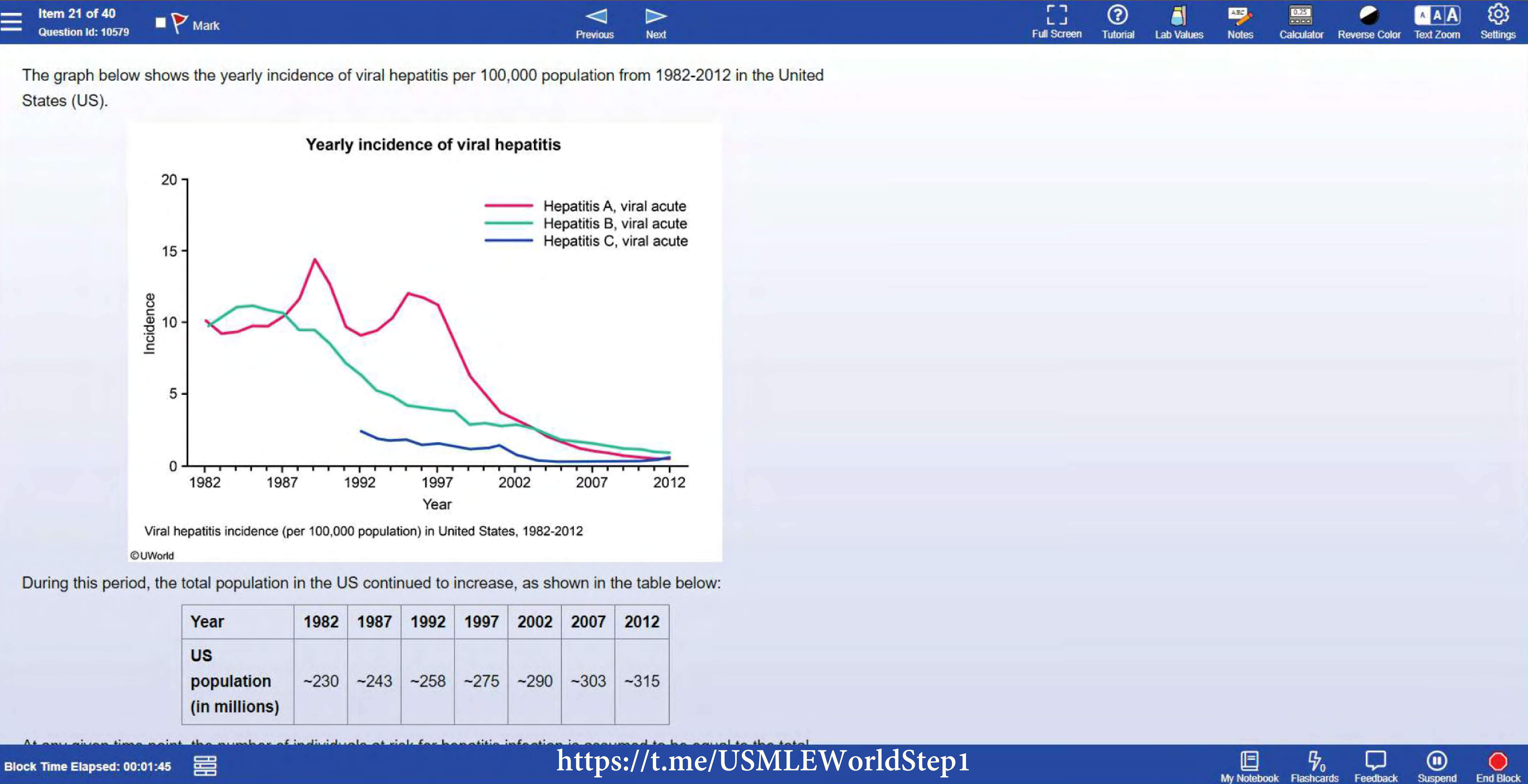
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The graph below shows the yearly incidence of viral hepatitis per 100,000 population from 1982-2012 in the United States (US).

Yearly incidence of viral hepatitis

20
15
10
5
0
Incidence
1982
1987
1992
1997
2002
2007
2012
Year
Hepatitis A, viral acute
Hepatitis B, viral acute
Hepatitis C, viral acute

Viral hepatitis incidence (per 100,000 population) in United States, 1982-2012

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During this period, the total population in the US continued to increase, as shown in the table below:

Year	1982	1987	1992	1997	2002	2007	2012
US population (in millions)	~230	~243	~258	~275	~290	~303	~315

At any given time point, the number of individuals at risk for hepatitis infection is assumed to be equal to the total

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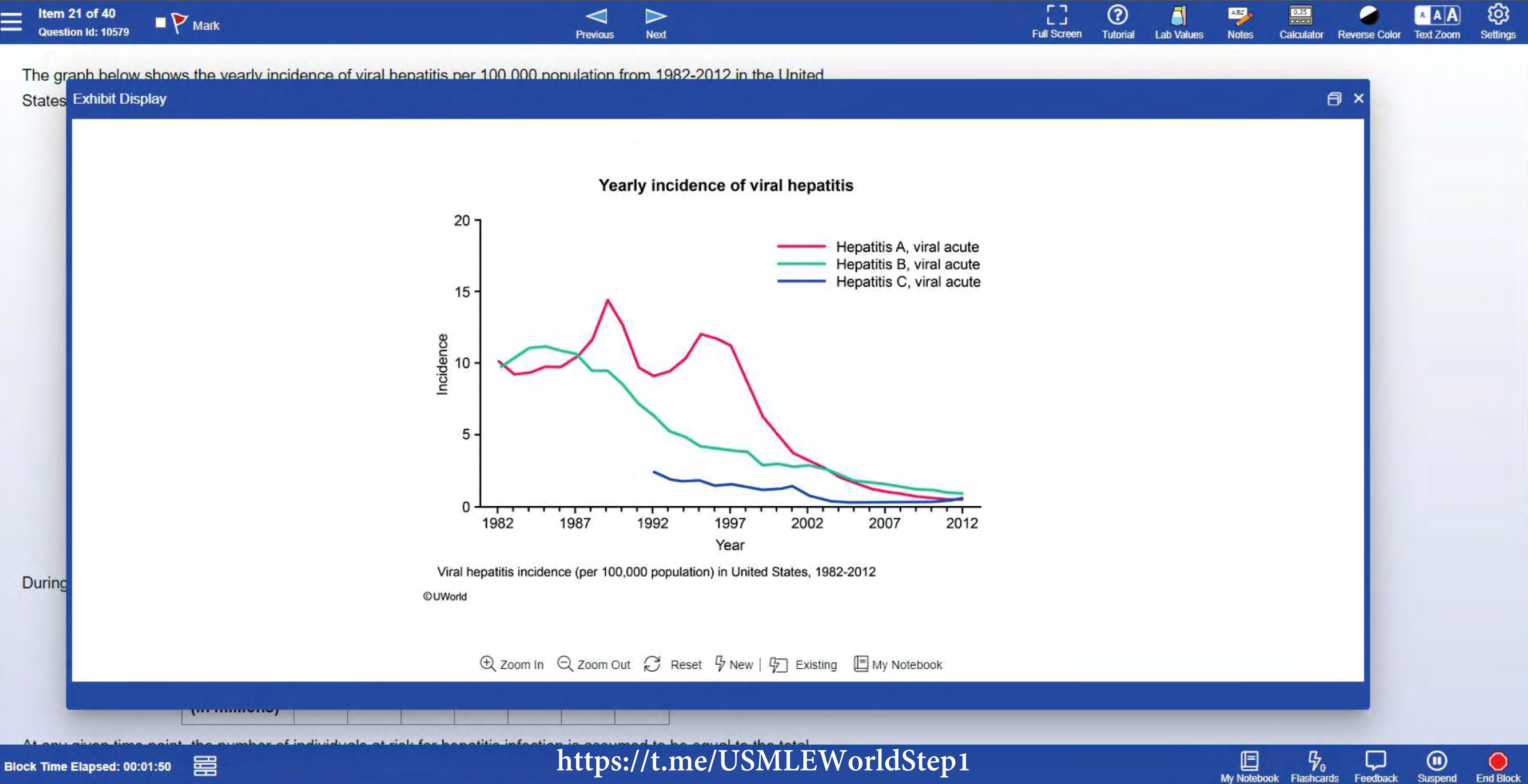
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The graph below shows the yearly incidence of viral hepatitis per 100,000 population from 1982-2012 in the United States

Exhibit Display

Yearly incidence of viral hepatitis

20
15
10
5
0
Incidence
Hepatitis A, viral acute
Hepatitis B, viral acute
Hepatitis C, viral acute
1982
1987
1992
1997
2002
2007
2012
Year

Viral hepatitis incidence (per 100,000 population) in United States, 1982-2012

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During

(in millions)

At any given time point, the number of individuals at risk for hepatitis infection is assumed to be equal to the total

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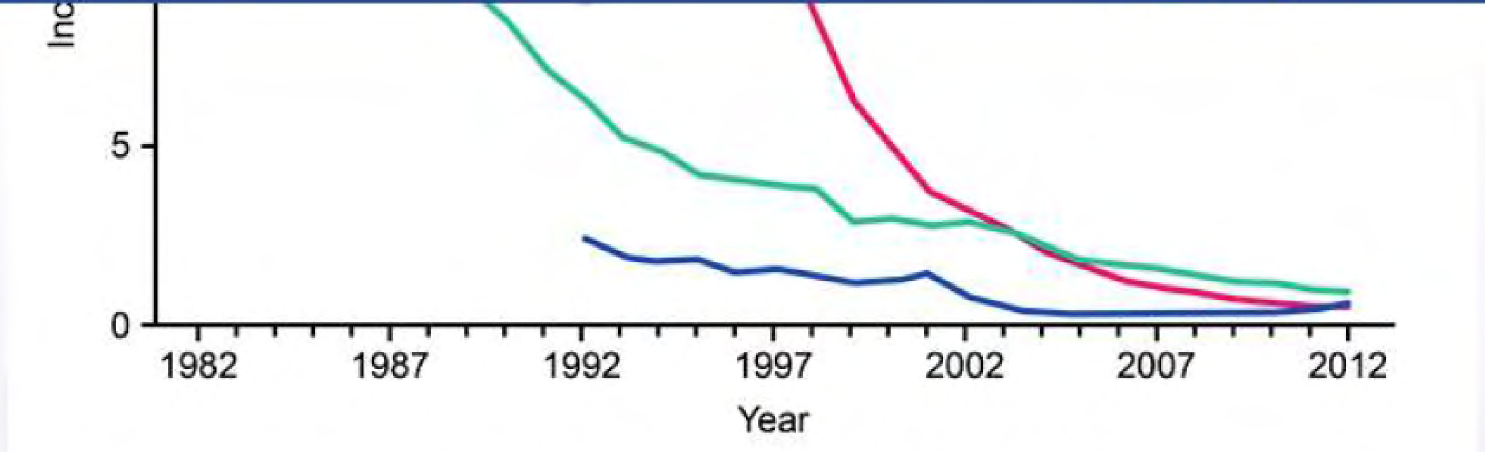

Viral hepatitis incidence (per 100,000 population) in United States, 1982-2012

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During this period, the total population in the US continued to increase, as shown in the table below:

Year	**1982**	**1987**	**1992**	**1997**	**2002**	**2007**	**2012**
US population (in millions)	~230	~243	~258	~275	~290	~303	~315

At any given time point, the number of individuals at risk for hepatitis infection is assumed to be equal to the total US population. Based on these data, which of the following is most likely to be true?

○ A. After 2006, hepatitis B prevalence surpassed hepatitis A and hepatitis C prevalence
○ B. In 1987, there were as many individuals with hepatitis A as with hepatitis B in the US
○ C. In 1989, there were more individuals with hepatitis A than with hepatitis B in the US
○ D. In 1997, there were more new cases of hepatitis A than of hepatitis B and C combined
○ E. The number of new cases of hepatitis A diagnosed in 1982 and 1998 were exactly the same

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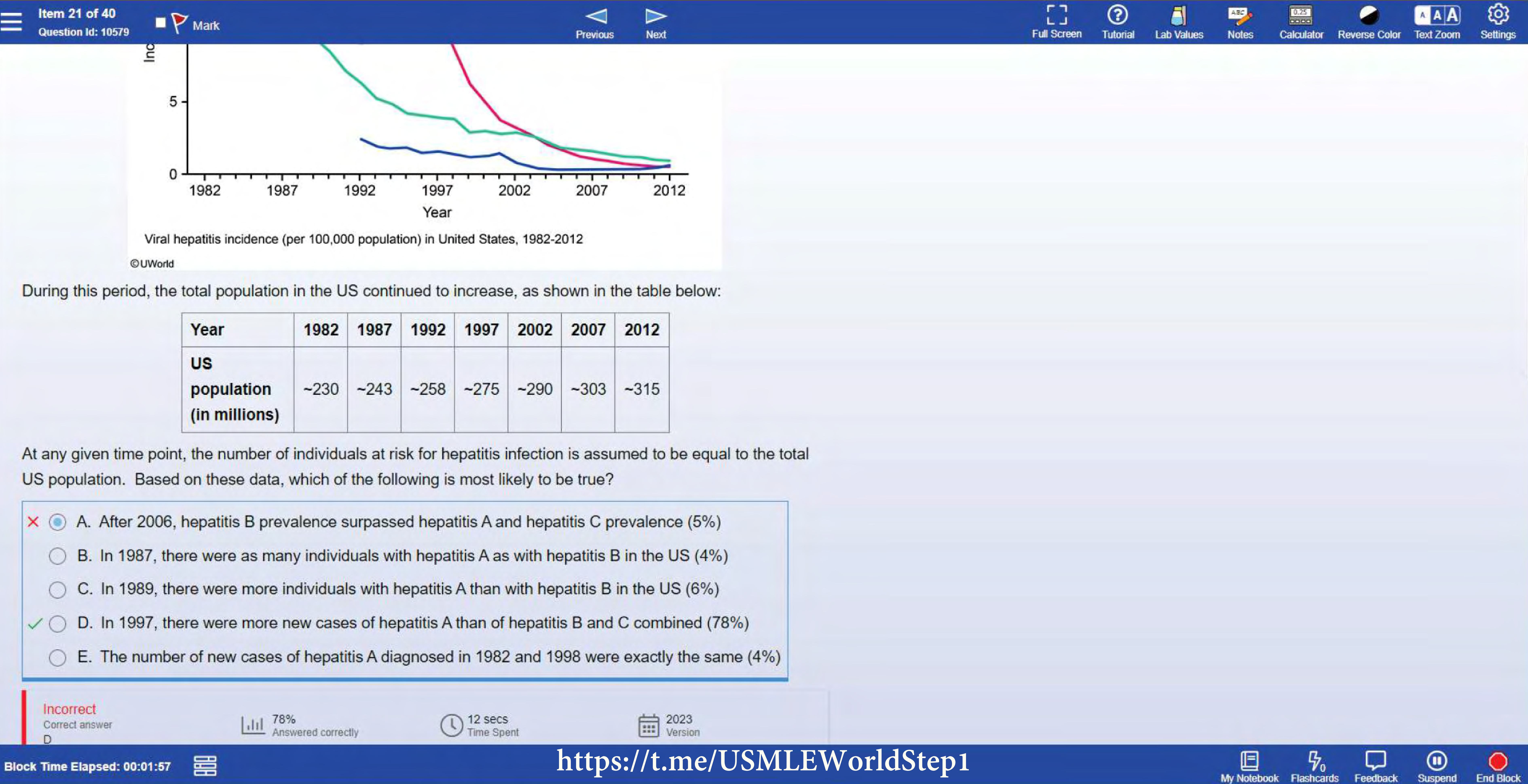
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Year

Viral hepatitis incidence (per 100,000 population) in United States, 1982-2012

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During this period, the total population in the US continued to increase, as shown in the table below:

Year	1982	1987	1992	1997	2002	2007	2012
US population (in millions)	~230	~243	~258	~275	~290	~303	~315

At any given time point, the number of individuals at risk for hepatitis infection is assumed to be equal to the total US population. Based on these data, which of the following is most likely to be true?

- × ● A. After 2006, hepatitis B prevalence surpassed hepatitis A and hepatitis C prevalence (5%)
- ○ B. In 1987, there were as many individuals with hepatitis A as with hepatitis B in the US (4%)
- ○ C. In 1989, there were more individuals with hepatitis A than with hepatitis B in the US (6%)
- ✓ ○ D. In 1997, there were more new cases of hepatitis A than of hepatitis B and C combined (78%)
- ○ E. The number of new cases of hepatitis A diagnosed in 1982 and 1998 were exactly the same (4%)

Incorrect
Correct answer
D

78%
Answered correctly

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Incidence corresponds to the number of **new** cases of a disease diagnosed in a population at risk over a given time period. In 1997, incidence was >10 new cases/100,000 population for hepatitis A virus (HAV), <5/100,000 for hepatitis B virus (HBV), and <3/100,000 for hepatitis C virus (HCV). Assuming, as instructed, that the entire United States (US) population is at risk (reasonable theory given low number of hepatitis cases among the total population), then, in 1997 (US population ~275 million):

New HAV cases in 1997 = >10 new cases/100,000 population × 275,000,000 population = >27,500
New HBV cases in 1997 = <5/100,000 × 275,000,000 = <13,750
New HCV cases in 1997 = <3/100,000 × 275,000,000 = <8,250

There were thousands more new HAV (>27,500) than HBV and HCV cases combined (<13,750 + <8,250 = <22,000). The calculations incorporating total population (included for completion) are not needed to answer the question.

After 2006, HBV incidence surpassed HAV and HCV incidence. However, no information can be deduced regarding **prevalence**, which is the **total** number of cases in the population **(Choice A)**. Compared to new HBV cases, there were approximately just as many **new** HAV cases in 1987 and more new HAV cases in 1989. However, the **total** number of HAV or HBV cases in the population cannot be calculated without additional information. In fact, there were likely more total cases (ie, higher prevalence) of HBV as it can progress to a chronic form **(Choices B and C)**.

A simplified diagram compares incidence and prevalence to adding new drops (incident cases) into a water-containing sink (prevalent cases).

(Choice E) HAV incidence **per 100,000 population** was similar in 1982 and 1998. However, the overall US population, and consequently the number of new HAV cases, was different. Assuming HAV incidence was ~10 new cases/100,000 population for both years, then, in 1982 (US population ~230 million):

New HAV cases in 1982 = 10/100,000 × 230,000,000 = 23,000

Also, in 1998 (US population ~275 million at least):

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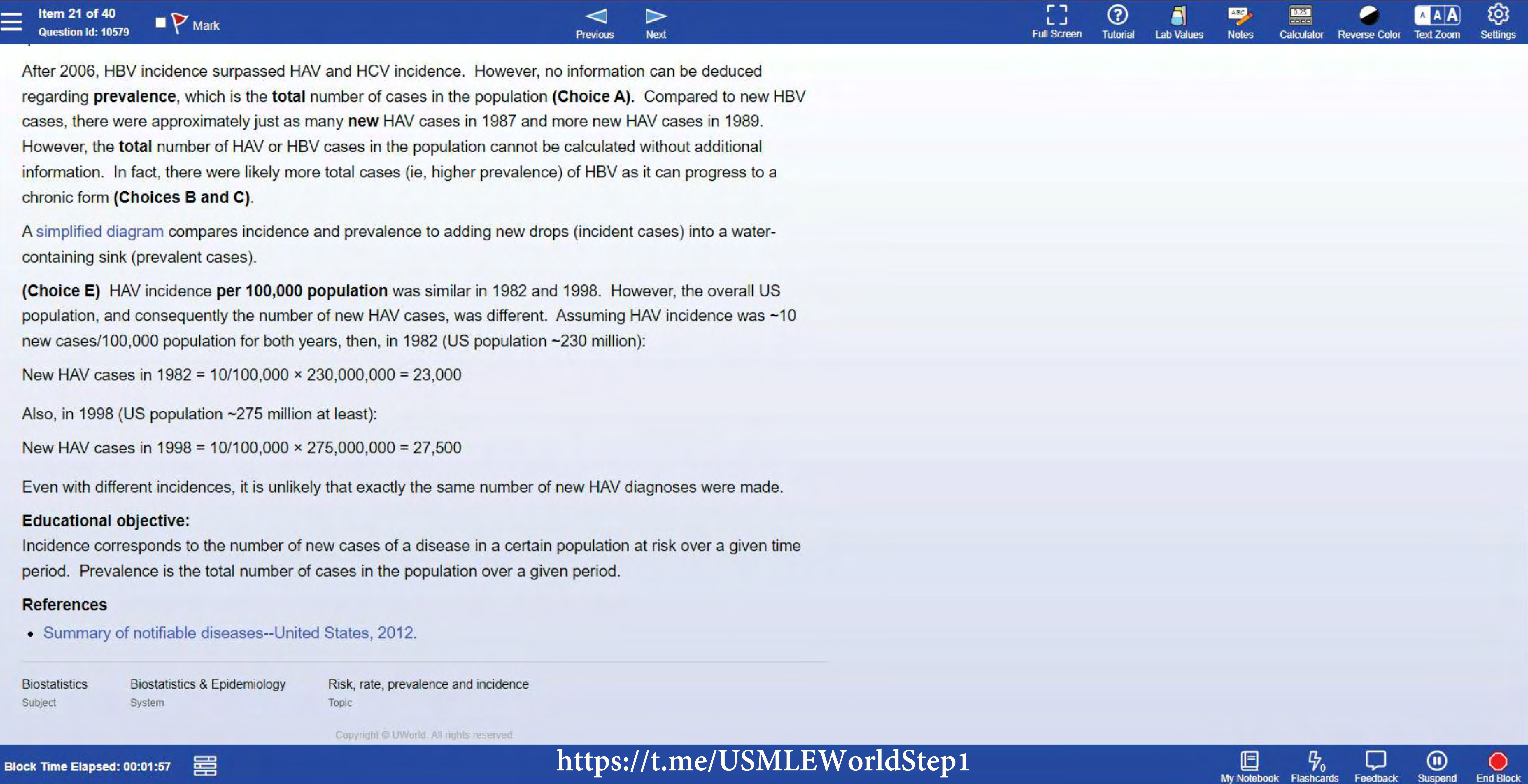
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A simplified diagram compares incidence and prevalence to adding new drops (incident cases) into a water-containing sink (prevalent cases).

(Choice E) HAV incidence **per 100,000 population** was similar in 1982 and 1998. However, the overall US population, and consequently the number of new HAV cases, was different. Assuming HAV incidence was ~10 new cases/100,000 population for both years, then, in 1982 (US population ~230 million):

New HAV cases in 1982 = 10/100,000 × 230,000,000 = 23,000

Also, in 1998 (US population ~275 million at least):

New HAV cases in 1998 = 10/100,000 × 275,000,000 = 27,500

Even with different incidences, it is unlikely that exactly the same number of new HAV diagnoses were made.

Educational objective:

Incidence corresponds to the number of new cases of a disease in a certain population at risk over a given time period. Prevalence is the total number of cases in the population over a given period.

References

- Summary of notifiable diseases--United States, 2012.

Biostatistics	Biostatistics & Epidemiology	Risk, rate, prevalence and incidence
Subject	System	Topic

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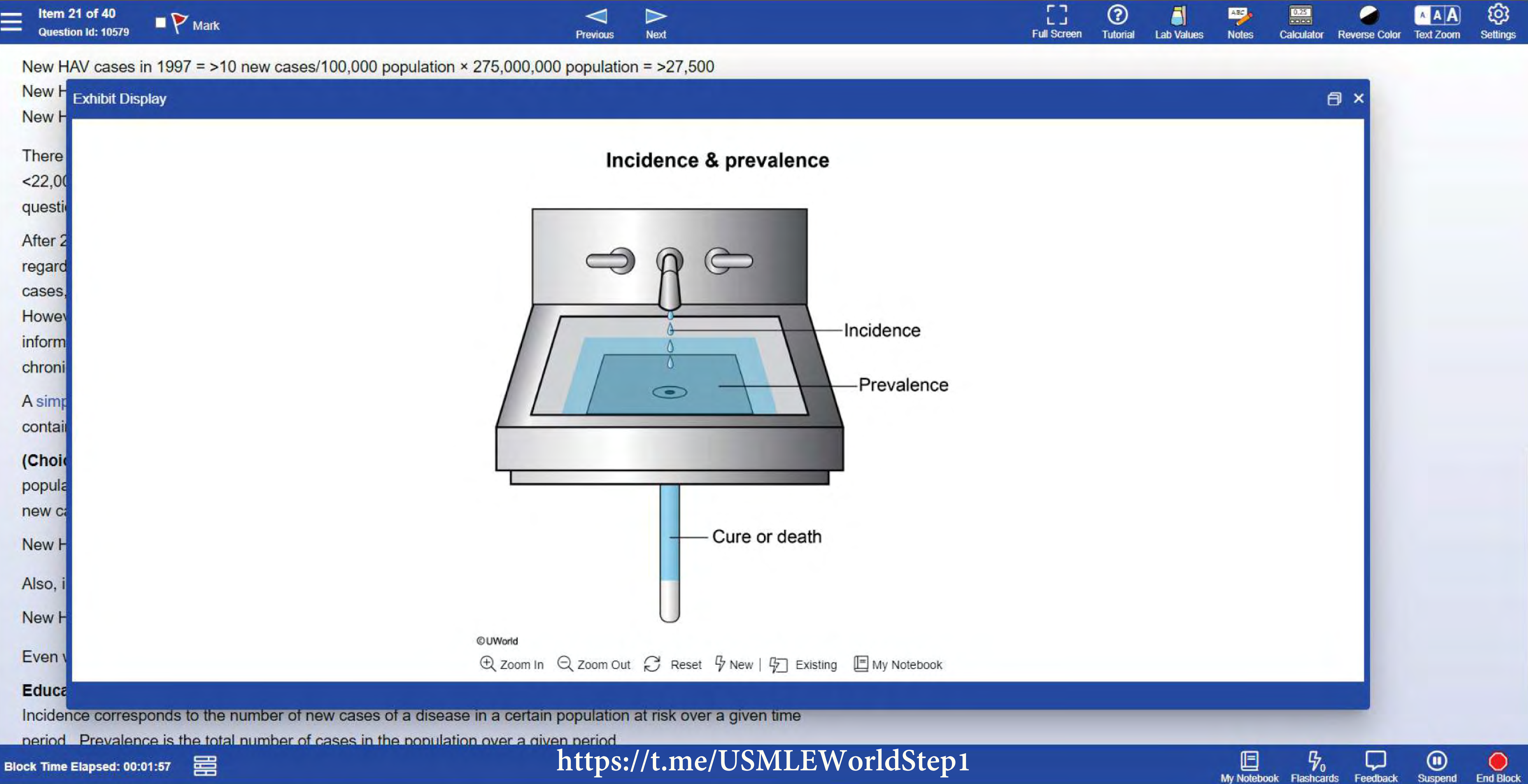
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New HAV cases in 1997 = >10 new cases/100,000 population × 275,000,000 population = >27,500

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Incidence corresponds to the number of new cases of a disease in a certain population at risk over a given time period. Prevalence is the total number of cases in the population over a given period.

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A large cohort study is conducted to assess the association between smoking and squamous cell carcinoma of the esophagus among middle-aged Chinese men. During 10 years of follow-up, smokers have 5 times the risk of esophageal carcinoma compared to non-smokers (relative risk = 5.0, 95% confidence interval = 2.9-7.1). According to the study results, what percentage of squamous cell carcinoma of the esophagus in smokers can be attributed to smoking?

- ○ A. 25%
- ○ B. 50%
- ○ C. 70%
- ○ D. 80%
- ○ E. 90%

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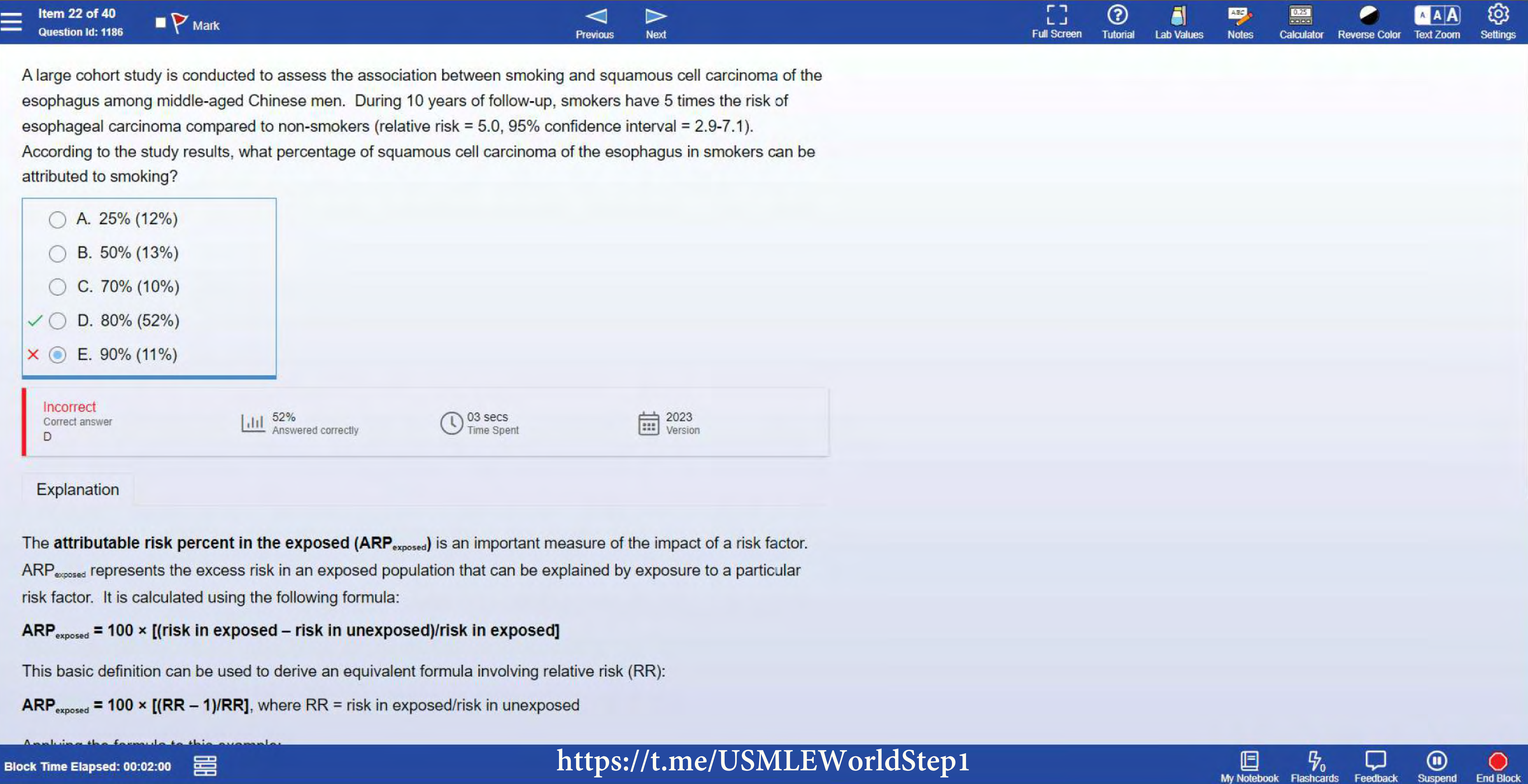
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○ A. 25% (12%)
○ B. 50% (13%)
○ C. 70% (10%)
✓ ○ D. 80% (52%)
✗ ● E. 90% (11%)

Incorrect
Correct answer
D

52%
Answered correctly

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Time Spent

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Explanation

The **attributable risk percent in the exposed (ARP$_{exposed}$)** is an important measure of the impact of a risk factor. ARP$_{exposed}$ represents the excess risk in an exposed population that can be explained by exposure to a particular risk factor. It is calculated using the following formula:

ARP$_{exposed}$ = 100 × [(risk in exposed – risk in unexposed)/risk in exposed]

This basic definition can be used to derive an equivalent formula involving relative risk (RR):

ARP$_{exposed}$ = 100 × [(RR – 1)/RR], where RR = risk in exposed/risk in unexposed

Applying the formula to this example:

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D
Answered correctly
Time Spent
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Explanation

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$ARP_{exposed}$ = 100 × [(risk in exposed – risk in unexposed)/risk in exposed]

This basic definition can be used to derive an equivalent formula involving relative risk (RR):

$ARP_{exposed}$ = 100 × [(RR – 1)/RR], where RR = risk in exposed/risk in unexposed

Applying the formula to this example:

$ARP_{exposed}$ = 100 × [(RR – 1)/RR] = 100 × [(5 – 1)/5] = 100 × (4/5) = 100 × 0.8 = 80%

Therefore, according to the study results, 80% of esophageal squamous cell carcinoma cases in smokers were attributable to smoking.

The $ARP_{exposed}$ is related to the attributable risk (AR), which is simply the difference between risk in the exposed and risk in the unexposed.

Educational objective:

The attributable risk percent (ARP) in the exposed represents the excess risk in the exposed population that can be attributed to the risk factor. It can be easily derived from the relative risk (RR) using the formula: $ARP_{exposed}$ = 100 × [(RR – 1)/RR].

Biostatistics	Biostatistics & Epidemiology	Risk
Subject	System	Topic

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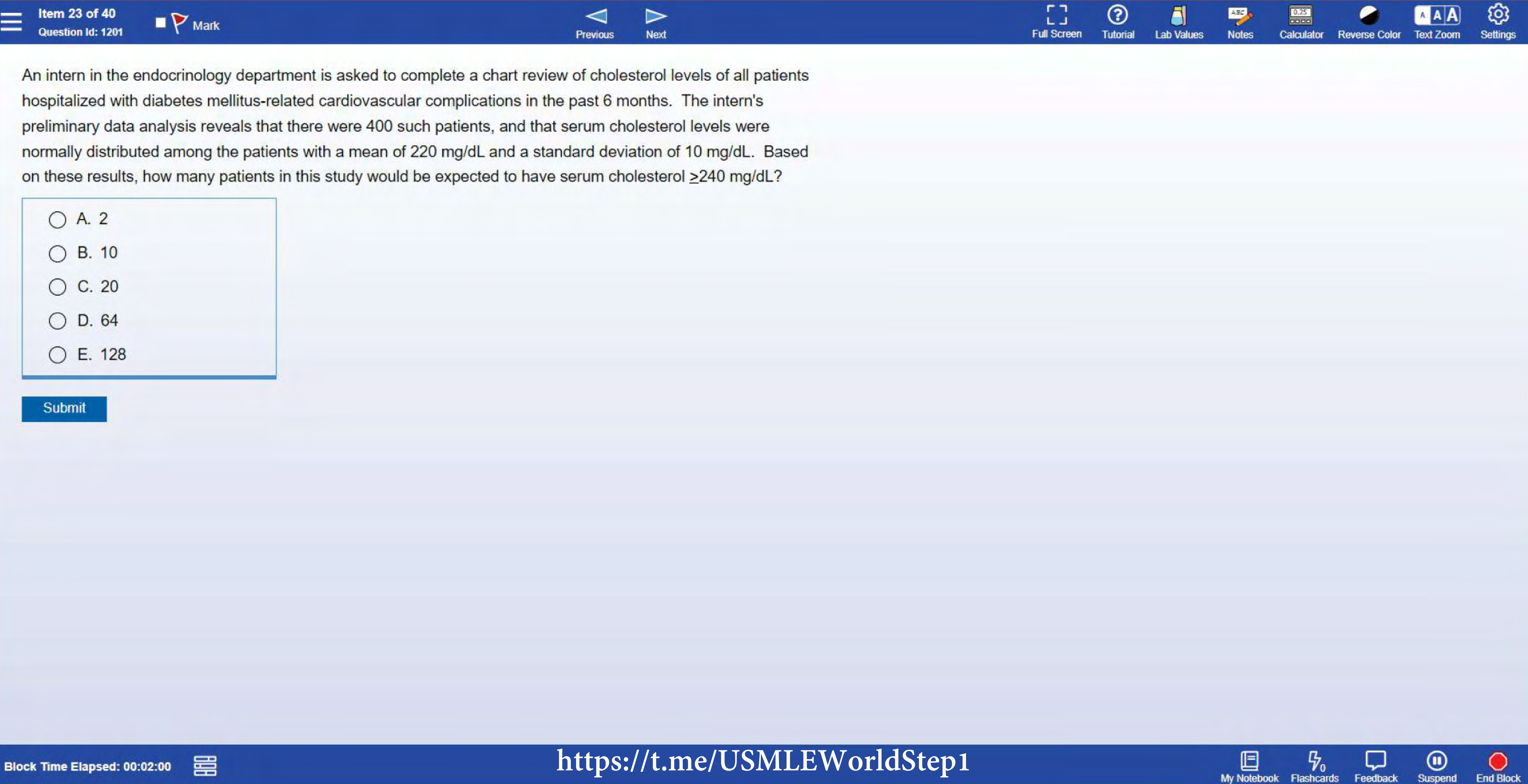
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An intern in the endocrinology department is asked to complete a chart review of cholesterol levels of all patients hospitalized with diabetes mellitus-related cardiovascular complications in the past 6 months. The intern's preliminary data analysis reveals that there were 400 such patients, and that serum cholesterol levels were normally distributed among the patients with a mean of 220 mg/dL and a standard deviation of 10 mg/dL. Based on these results, how many patients in this study would be expected to have serum cholesterol $\geq$240 mg/dL?

- ○ A. 2
- ○ B. 10
- ○ C. 20
- ○ D. 64
- ○ E. 128

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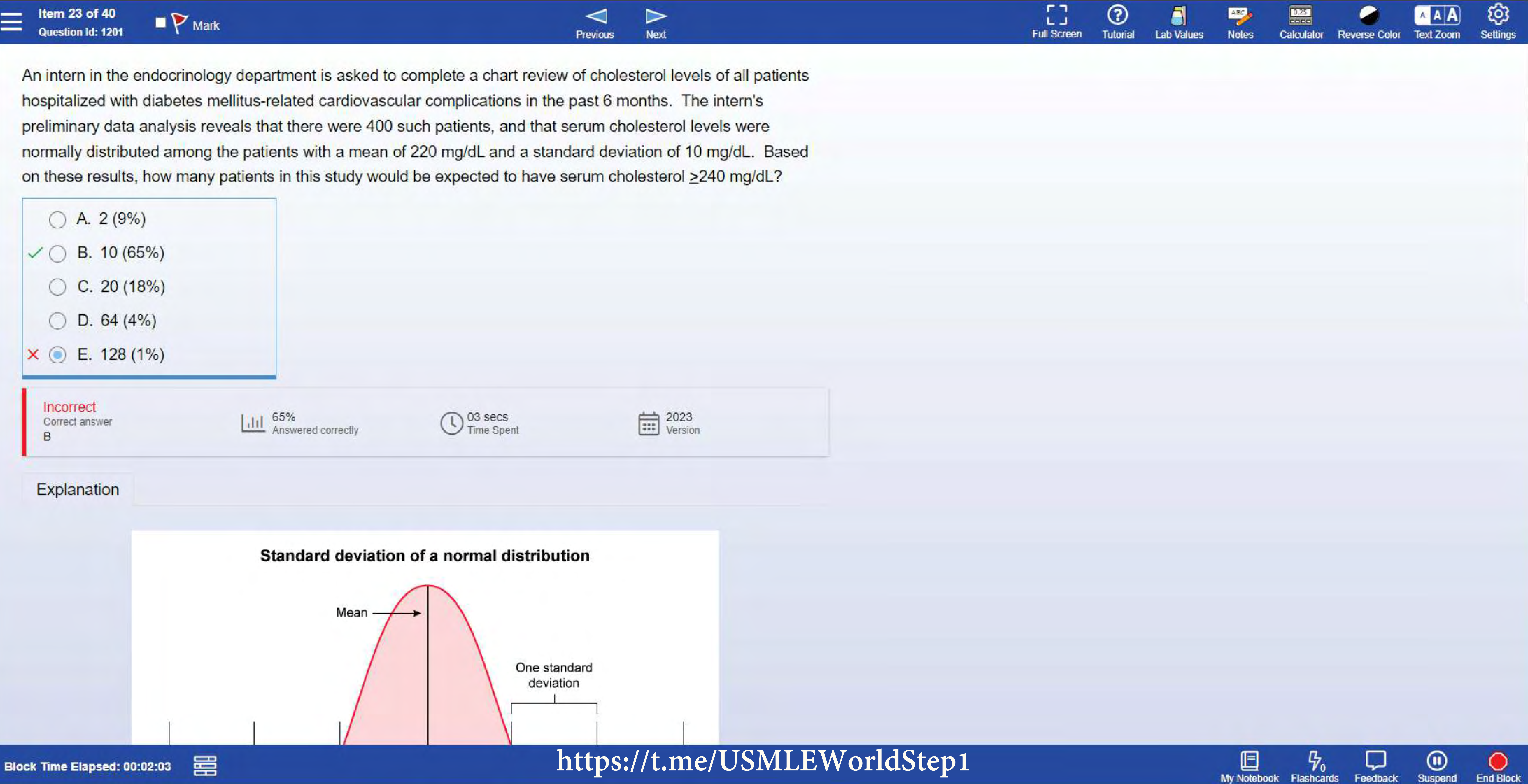
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An intern in the endocrinology department is asked to complete a chart review of cholesterol levels of all patients hospitalized with diabetes mellitus-related cardiovascular complications in the past 6 months. The intern's preliminary data analysis reveals that there were 400 such patients, and that serum cholesterol levels were normally distributed among the patients with a mean of 220 mg/dL and a standard deviation of 10 mg/dL. Based on these results, how many patients in this study would be expected to have serum cholesterol ≥240 mg/dL?

○ A. 2 (9%)
✓ ○ B. 10 (65%)
○ C. 20 (18%)
○ D. 64 (4%)
✗ ● E. 128 (1%)

Incorrect
Correct answer
B

65%
Answered correctly

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Explanation

Standard deviation of a normal distribution

Mean
One standard deviation

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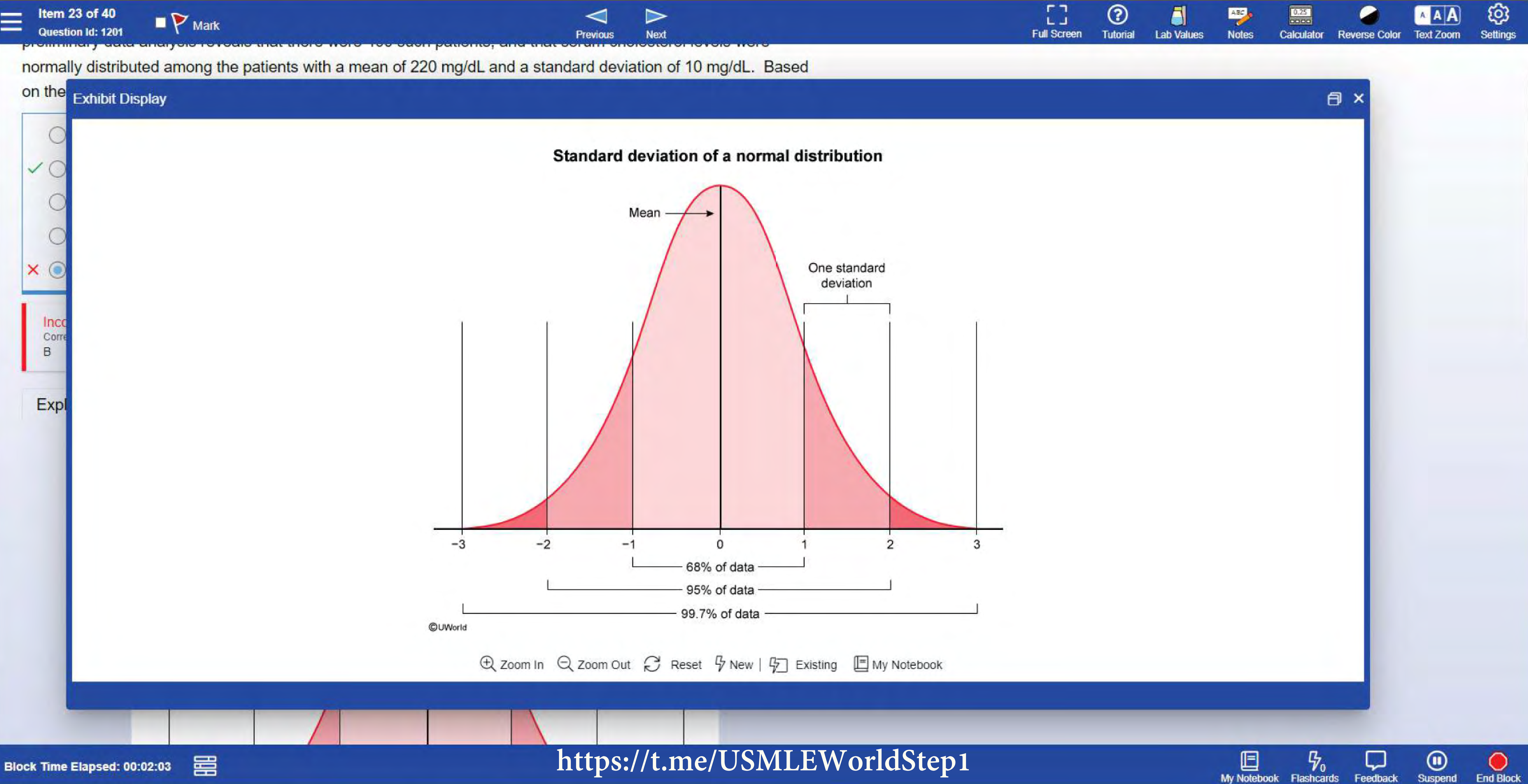
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normally distributed among the patients with a mean of 220 mg/dL and a standard deviation of 10 mg/dL. Based

on the

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Standard deviation of a normal distribution

Mean
One standard deviation
−3
−2
−1
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1
2
3
68% of data
95% of data
99.7% of data
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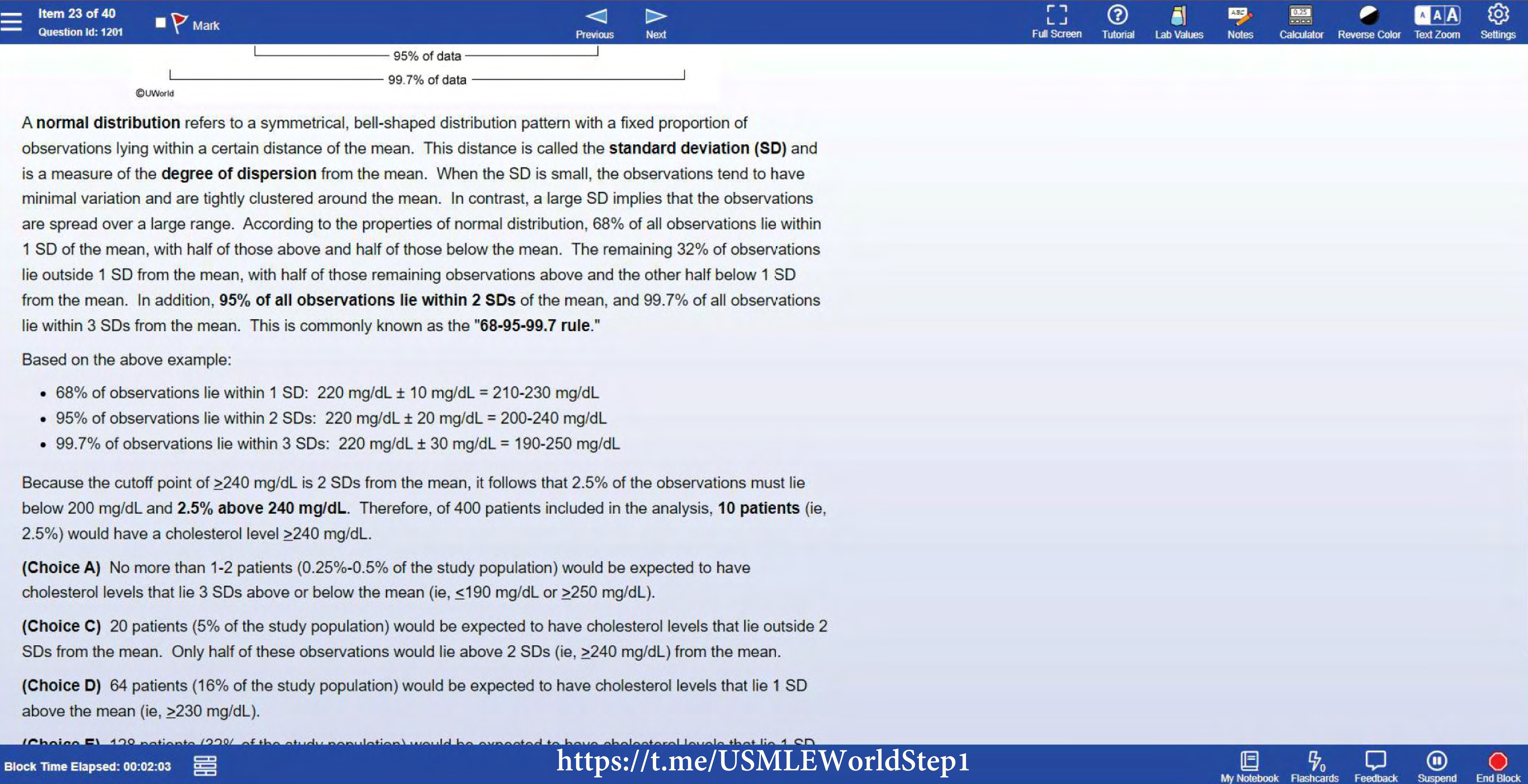
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95% of data
99.7% of data
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A **normal distribution** refers to a symmetrical, bell-shaped distribution pattern with a fixed proportion of observations lying within a certain distance of the mean. This distance is called the **standard deviation (SD)** and is a measure of the **degree of dispersion** from the mean. When the SD is small, the observations tend to have minimal variation and are tightly clustered around the mean. In contrast, a large SD implies that the observations are spread over a large range. According to the properties of normal distribution, 68% of all observations lie within 1 SD of the mean, with half of those above and half of those below the mean. The remaining 32% of observations lie outside 1 SD from the mean, with half of those remaining observations above and the other half below 1 SD from the mean. In addition, **95% of all observations lie within 2 SDs** of the mean, and 99.7% of all observations lie within 3 SDs from the mean. This is commonly known as the "**68-95-99.7 rule**."

Based on the above example:

- 68% of observations lie within 1 SD: 220 mg/dL ± 10 mg/dL = 210-230 mg/dL
- 95% of observations lie within 2 SDs: 220 mg/dL ± 20 mg/dL = 200-240 mg/dL
- 99.7% of observations lie within 3 SDs: 220 mg/dL ± 30 mg/dL = 190-250 mg/dL

Because the cutoff point of $\geq$240 mg/dL is 2 SDs from the mean, it follows that 2.5% of the observations must lie below 200 mg/dL and **2.5% above 240 mg/dL**. Therefore, of 400 patients included in the analysis, **10 patients** (ie, 2.5%) would have a cholesterol level $\geq$240 mg/dL.

(Choice A) No more than 1-2 patients (0.25%-0.5% of the study population) would be expected to have cholesterol levels that lie 3 SDs above or below the mean (ie, $\leq$190 mg/dL or $\geq$250 mg/dL).

(Choice C) 20 patients (5% of the study population) would be expected to have cholesterol levels that lie outside 2 SDs from the mean. Only half of these observations would lie above 2 SDs (ie, $\geq$240 mg/dL) from the mean.

(Choice D) 64 patients (16% of the study population) would be expected to have cholesterol levels that lie 1 SD above the mean (ie, $\geq$230 mg/dL).

(Choice E) 128 patients (32% of the study population) would be expected to have cholesterol levels that lie 1 SD from the mean. In addition, **95% of all observations lie within 2 SDs** of the mean, and 99.7% of all observations lie within 3 SDs from the mean. This is commonly known as the "**68-95-99.7 rule**."

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(Choice A) No more than 1-2 patients (0.25%-0.5% of the study population) would be expected to have cholesterol levels that lie 3 SDs above or below the mean (ie, ≤190 mg/dL or ≥250 mg/dL).

(Choice C) 20 patients (5% of the study population) would be expected to have cholesterol levels that lie outside 2 SDs from the mean. Only half of these observations would lie above 2 SDs (ie, ≥240 mg/dL) from the mean.

(Choice D) 64 patients (16% of the study population) would be expected to have cholesterol levels that lie 1 SD above the mean (ie, ≥230 mg/dL).

(Choice E) 128 patients (32% of the study population) would be expected to have cholesterol levels that lie 1 SD above or below the mean (ie, ≥230 mg/dL or ≤210 mg/dL).

Educational objective:

In a normal (bell-shaped) distribution: 68% of all values are within 1 standard deviation from the mean; 95% of all values are within 2 standard deviations from the mean; 99.7% of all values are within 3 standard deviations from the mean.

Biostatistics	Biostatistics & Epidemiology	Normal distribution
Subject	System	Topic

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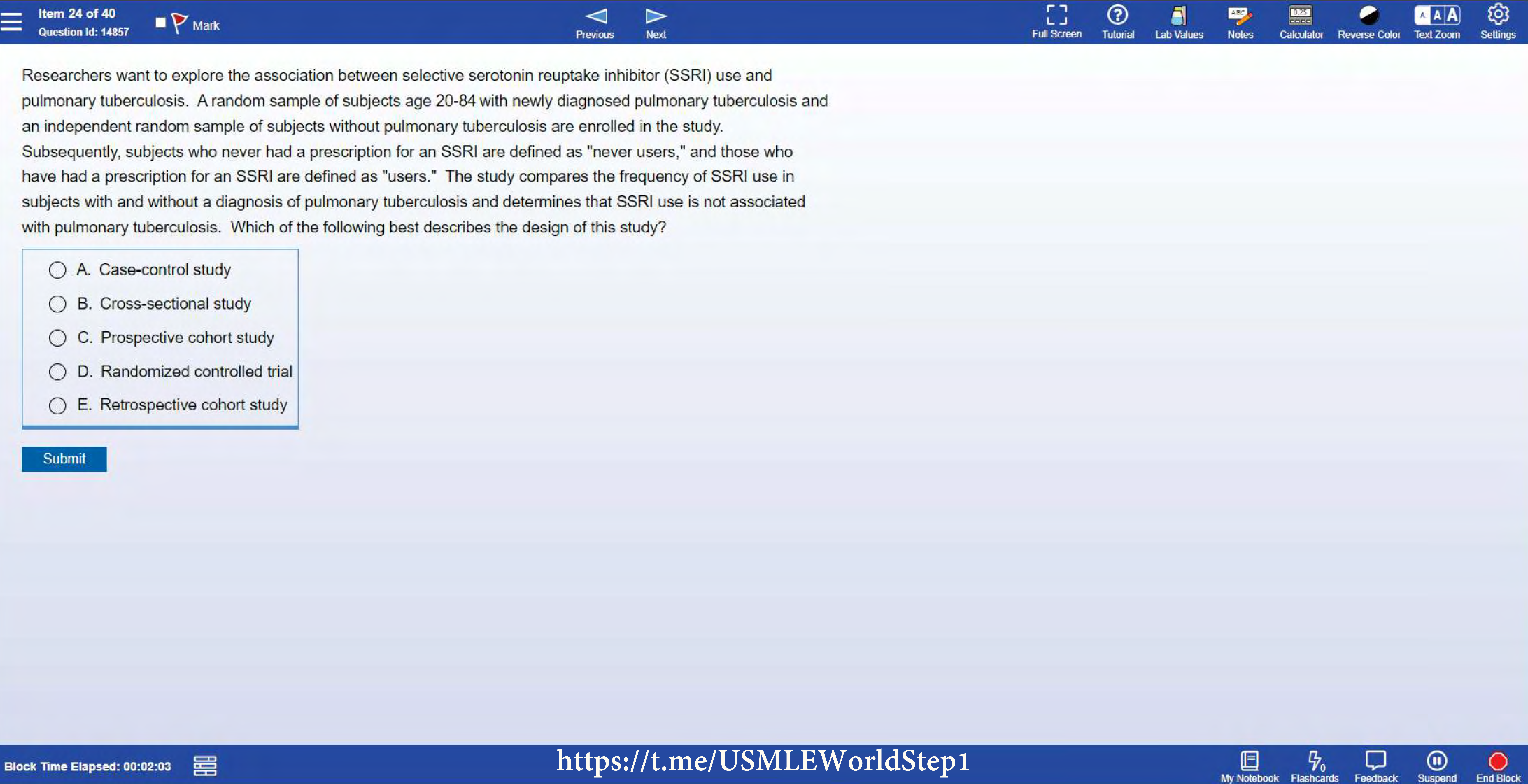
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Researchers want to explore the association between selective serotonin reuptake inhibitor (SSRI) use and pulmonary tuberculosis. A random sample of subjects age 20-84 with newly diagnosed pulmonary tuberculosis and an independent random sample of subjects without pulmonary tuberculosis are enrolled in the study. Subsequently, subjects who never had a prescription for an SSRI are defined as "never users," and those who have had a prescription for an SSRI are defined as "users." The study compares the frequency of SSRI use in subjects with and without a diagnosis of pulmonary tuberculosis and determines that SSRI use is not associated with pulmonary tuberculosis. Which of the following best describes the design of this study?

- ○ A. Case-control study
- ○ B. Cross-sectional study
- ○ C. Prospective cohort study
- ○ D. Randomized controlled trial
- ○ E. Retrospective cohort study

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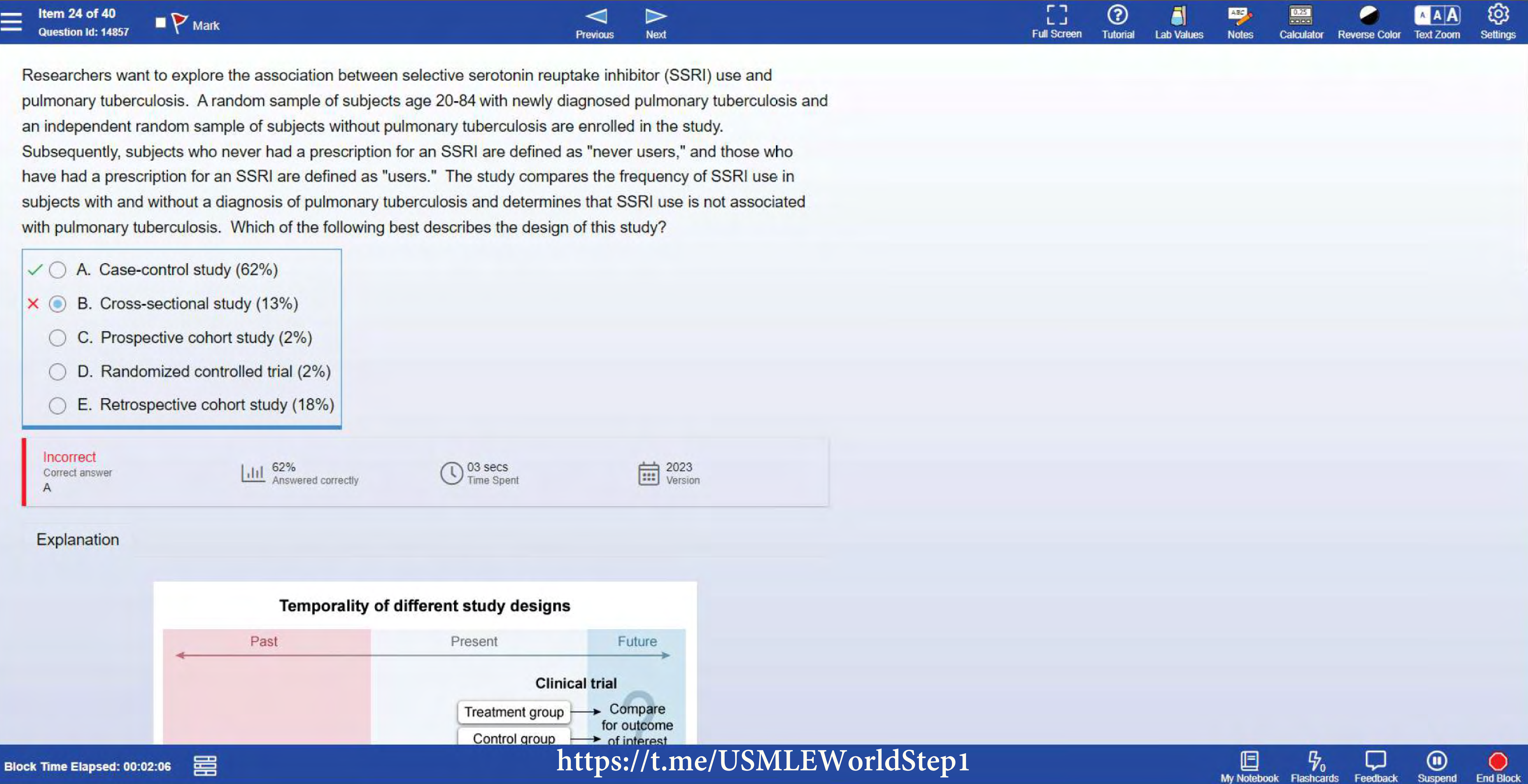
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✓ ○ A. Case-control study (62%)

✗ ● B. Cross-sectional study (13%)

○ C. Prospective cohort study (2%)

○ D. Randomized controlled trial (2%)

○ E. Retrospective cohort study (18%)

Incorrect
Correct answer
A

62%
Answered correctly

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Explanation

Temporality of different study designs

Past
Present
Future
Clinical trial
Treatment group
Control group
Compare for outcome of interest

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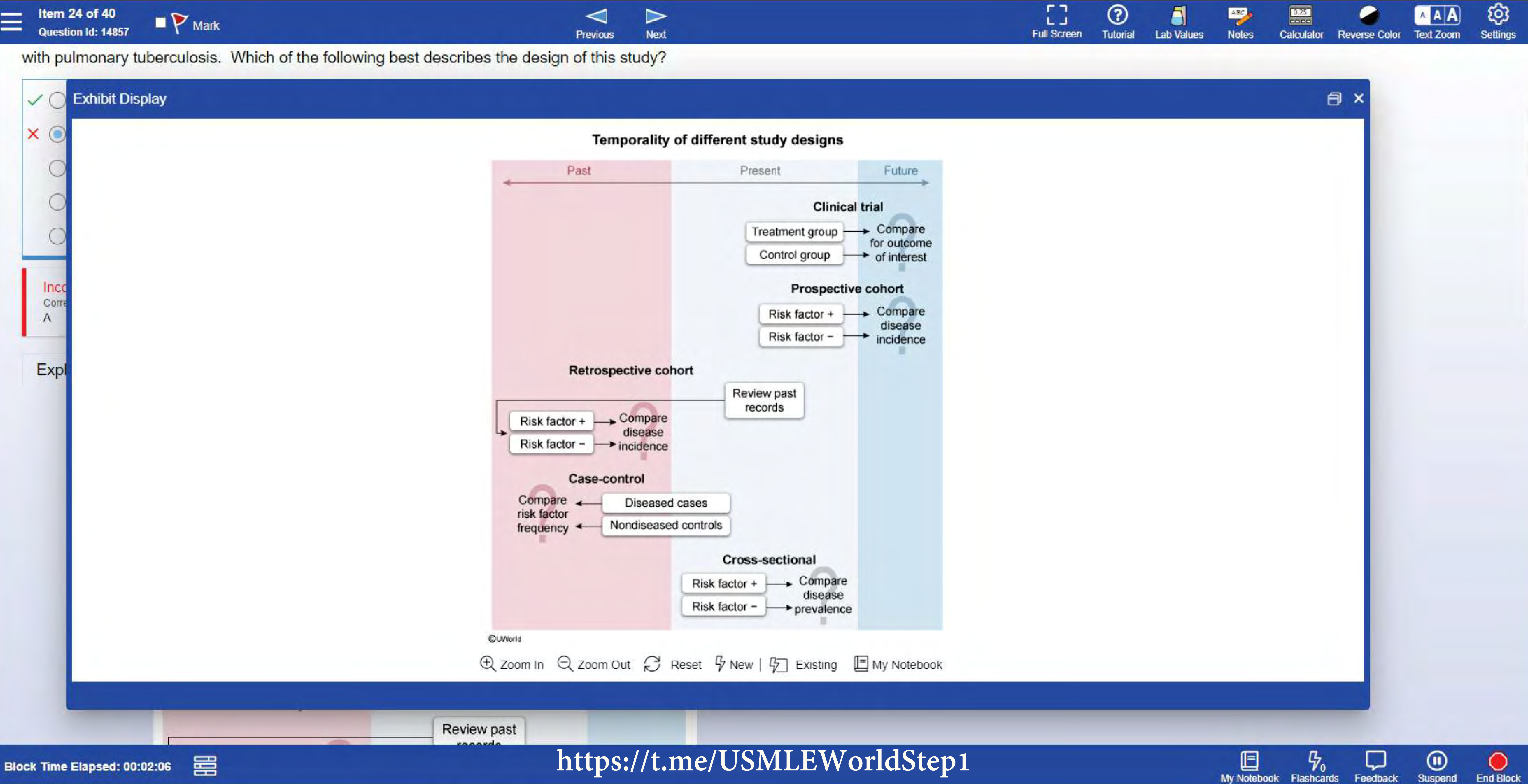

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with pulmonary tuberculosis. Which of the following best describes the design of this study?

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Exhibit Display

Temporality of different study designs

Past
Present
Future
Clinical trial
Treatment group
Control group
Compare for outcome of interest
Prospective cohort
Risk factor +
Risk factor –
Compare disease incidence
Retrospective cohort
Review past records
Risk factor +
Risk factor –
Compare disease incidence
Case-control
Compare risk factor frequency
Diseased cases
Nondiseased controls
Cross-sectional
Risk factor +
Risk factor –
Compare disease prevalence
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New
Existing
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Review past
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Risk factor
prevalence

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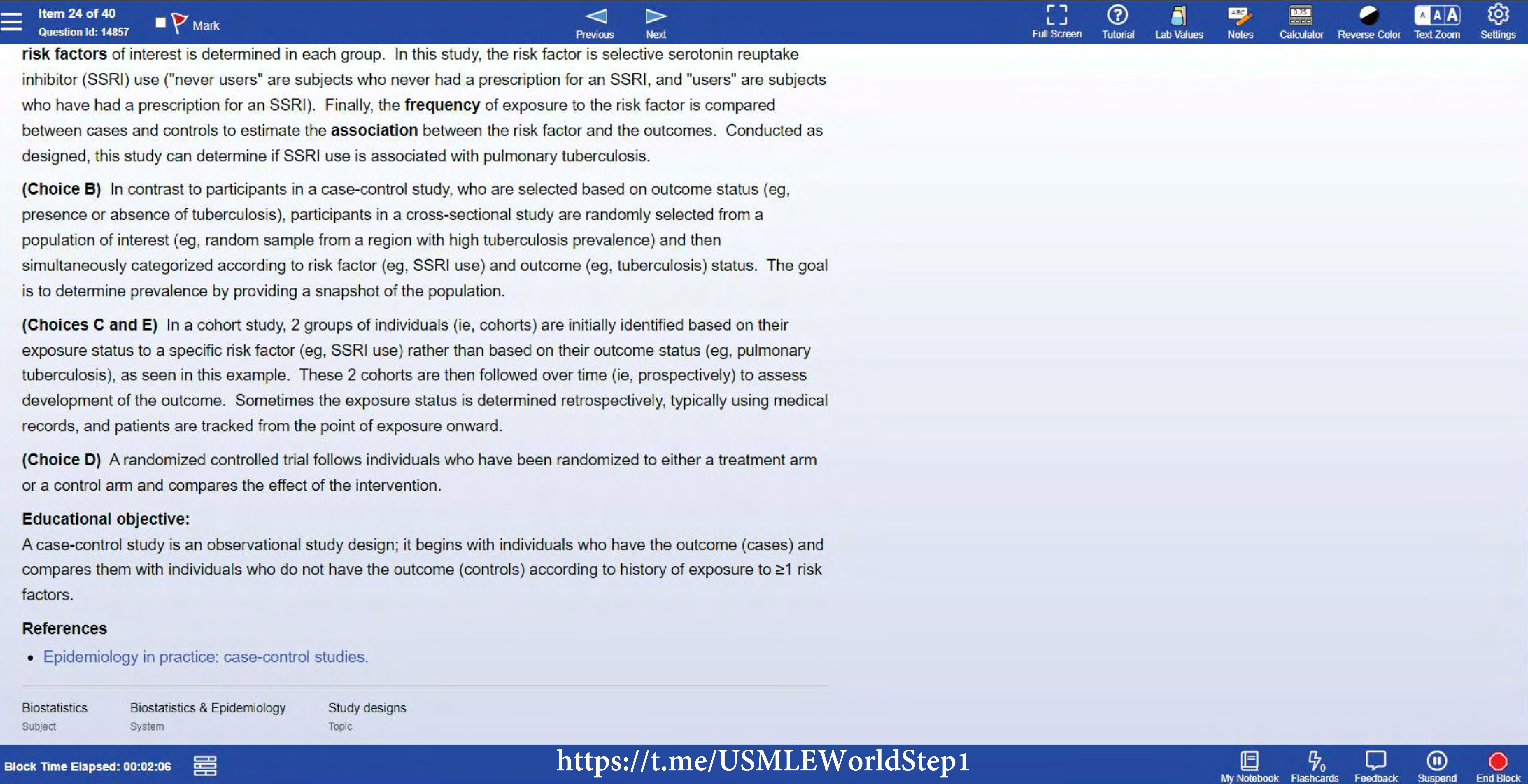
Research studies are broadly classified as having an observational or experimental design depending on the control the researcher has over the independent variables (eg, exposure to risk factors, treatments).

- In **observational studies** (eg, case series, case-control studies, cohort studies, cross-sectional studies), the researcher has **no control** over the independent variables (eg, exposures, risk factors).
- In **experimental studies** (eg, randomized controlled trials), the researcher **controls** and randomly assigns the independent variables (eg, treatments, interventions).

A **case-control** study is an observational design in which potential participants are initially identified as **cases** or **controls** according to the **dependent variable or outcome** (eg, disease of interest). In the study described above, subjects age 20-84 newly diagnosed with pulmonary tuberculosis are cases, and subjects without pulmonary tuberculosis are controls. Once cases and controls are identified, the presence of past exposure to ≥1 **risk factors** of interest is determined in each group. In this study, the risk factor is selective serotonin reuptake inhibitor (SSRI) use ("never users" are subjects who never had a prescription for an SSRI, and "users" are subjects who have had a prescription for an SSRI). Finally, the **frequency** of exposure to the risk factor is compared between cases and controls to estimate the **association** between the risk factor and the outcomes. Conducted as designed, this study can determine if SSRI use is associated with pulmonary tuberculosis.

(Choice B) In contrast to participants in a case-control study, who are selected based on outcome status (eg, presence or absence of tuberculosis), participants in a cross-sectional study are randomly selected from a population of interest (eg, random sample from a region with high tuberculosis prevalence) and then simultaneously categorized according to risk factor (eg, SSRI use) and outcome (eg, tuberculosis) status. The goal is to determine prevalence by providing a snapshot of the population.

(Choices C and E) In a cohort study, 2 groups of individuals (ie, cohorts) are initially identified based on their exposure status to a specific risk factor (eg, SSRI use) rather than based on their outcome status (eg, pulmonary tuberculosis), as seen in this example. These 2 cohorts are then followed over time (ie, prospectively) to assess development of the outcome. Sometimes the exposure status is determined retrospectively, typically using medical



risk factors of interest is determined in each group. In this study, the risk factor is selective serotonin reuptake inhibitor (SSRI) use ("never users" are subjects who never had a prescription for an SSRI, and "users" are subjects who have had a prescription for an SSRI). Finally, the **frequency** of exposure to the risk factor is compared between cases and controls to estimate the **association** between the risk factor and the outcomes. Conducted as designed, this study can determine if SSRI use is associated with pulmonary tuberculosis.

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(Choices C and E) In a cohort study, 2 groups of individuals (ie, cohorts) are initially identified based on their exposure status to a specific risk factor (eg, SSRI use) rather than based on their outcome status (eg, pulmonary tuberculosis), as seen in this example. These 2 cohorts are then followed over time (ie, prospectively) to assess development of the outcome. Sometimes the exposure status is determined retrospectively, typically using medical records, and patients are tracked from the point of exposure onward.

(Choice D) A randomized controlled trial follows individuals who have been randomized to either a treatment arm or a control arm and compares the effect of the intervention.

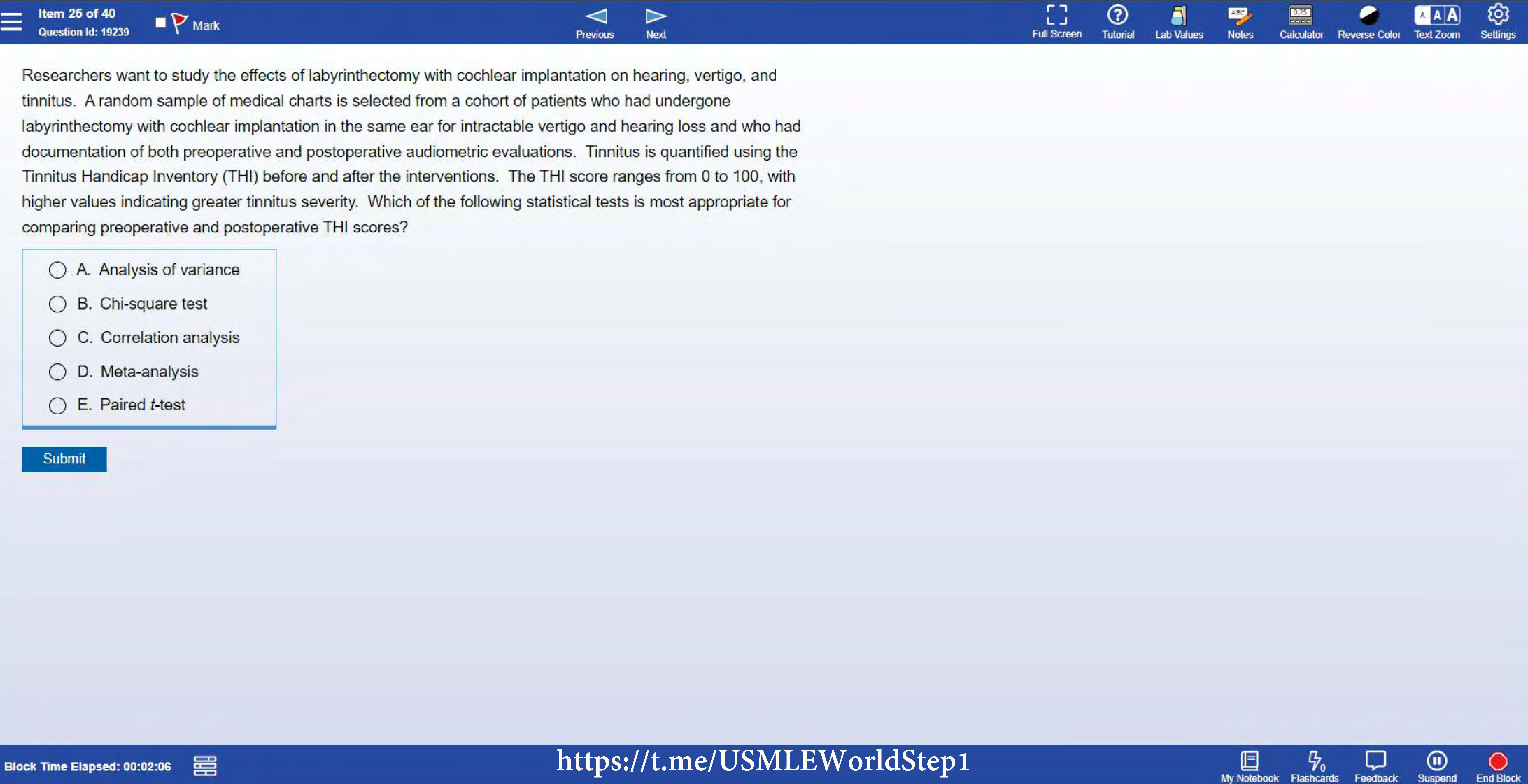
Educational objective:

A case-control study is an observational study design; it begins with individuals who have the outcome (cases) and compares them with individuals who do not have the outcome (controls) according to history of exposure to ≥1 risk factors.

References

- Epidemiology in practice: case-control studies.

Biostatistics	Biostatistics & Epidemiology	Study designs
Subject	System	Topic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Researchers want to study the effects of labyrinthectomy with cochlear implantation on hearing, vertigo, and tinnitus. A random sample of medical charts is selected from a cohort of patients who had undergone labyrinthectomy with cochlear implantation in the same ear for intractable vertigo and hearing loss and who had documentation of both preoperative and postoperative audiometric evaluations. Tinnitus is quantified using the Tinnitus Handicap Inventory (THI) before and after the interventions. The THI score ranges from 0 to 100, with higher values indicating greater tinnitus severity. Which of the following statistical tests is most appropriate for comparing preoperative and postoperative THI scores?

○ A. Analysis of variance
○ B. Chi-square test
○ C. Correlation analysis
○ D. Meta-analysis
○ E. Paired *t*-test

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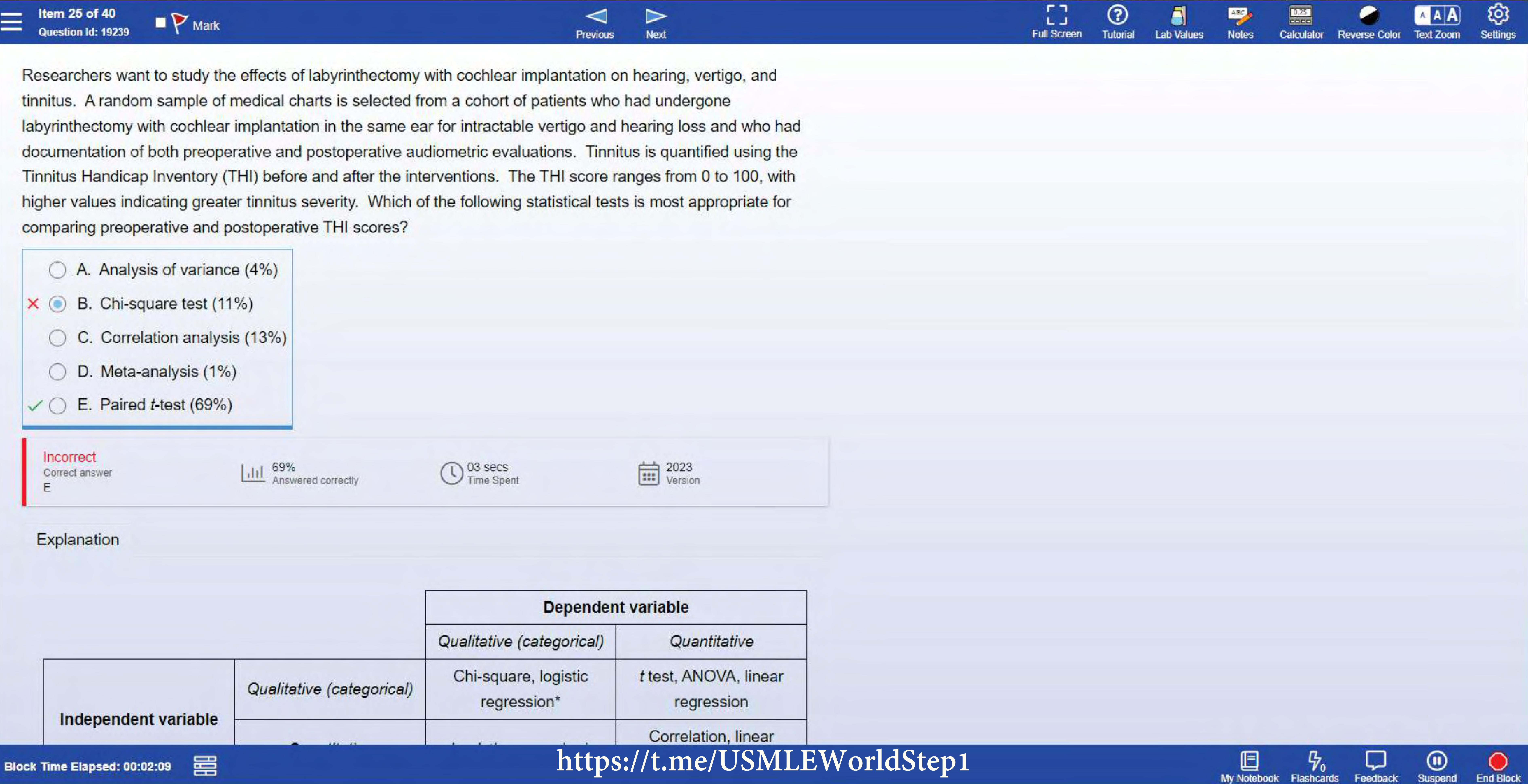
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- ○ A. Analysis of variance (4%)
- ✗ ● B. Chi-square test (11%)
- ○ C. Correlation analysis (13%)
- ○ D. Meta-analysis (1%)
- ✓ ○ E. Paired *t*-test (69%)

Incorrect
Correct answer
E

69%
Answered correctly

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Explanation

		Dependent variable	
		Qualitative (categorical)	*Quantitative*
Independent variable	*Qualitative (categorical)*	Chi-square, logistic regression*	*t* test, ANOVA, linear regression
			Correlation, linear

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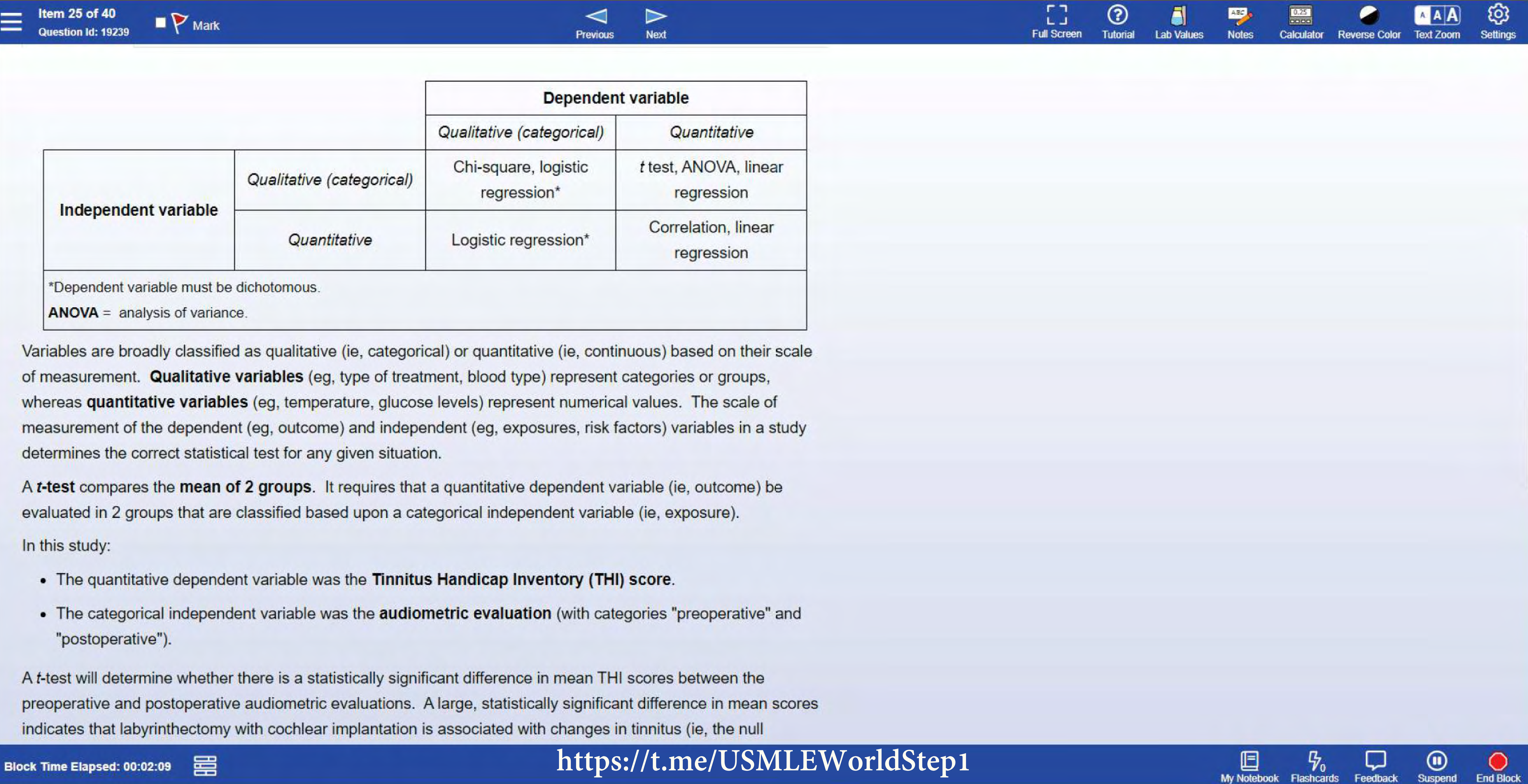
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		Dependent variable	
		Qualitative (categorical)	*Quantitative*
Independent variable	*Qualitative (categorical)*	Chi-square, logistic regression*	*t* test, ANOVA, linear regression
	Quantitative	Logistic regression*	Correlation, linear regression

*Dependent variable must be dichotomous.

ANOVA = analysis of variance.

Variables are broadly classified as qualitative (ie, categorical) or quantitative (ie, continuous) based on their scale of measurement. **Qualitative variables** (eg, type of treatment, blood type) represent categories or groups, whereas **quantitative variables** (eg, temperature, glucose levels) represent numerical values. The scale of measurement of the dependent (eg, outcome) and independent (eg, exposures, risk factors) variables in a study determines the correct statistical test for any given situation.

A ***t*-test** compares the **mean of 2 groups**. It requires that a quantitative dependent variable (ie, outcome) be evaluated in 2 groups that are classified based upon a categorical independent variable (ie, exposure).

In this study:

- The quantitative dependent variable was the **Tinnitus Handicap Inventory (THI) score**.
- The categorical independent variable was the **audiometric evaluation** (with categories "preoperative" and "postoperative").

A *t*-test will determine whether there is a statistically significant difference in mean THI scores between the preoperative and postoperative audiometric evaluations. A large, statistically significant difference in mean scores indicates that labyrinthectomy with cochlear implantation is associated with changes in tinnitus (ie, the null postoperative").

A *t*-test will determine whether there is a statistically significant difference in mean THI scores between the preoperative and postoperative audiometric evaluations. A large, statistically significant difference in mean scores indicates that labyrinthectomy with cochlear implantation is associated with changes in tinnitus (ie, the null hypothesis is rejected).

There are 2 types of *t*-tests: the independent samples *t*-test (used when 2 groups are independent) and the **paired *t*-test** (used with 2 related groups with matched pairs). Matched groups are formed when each observation in one group is paired with an observation from the other group. Examples include a study in which individuals have been assessed twice (eg, before and after an intervention) and one in which 2 groups of individuals have been matched based on certain attributes (eg, age, severity of disease). In this case, THI scores are assessed twice for each patient (preoperative and postoperative audiometric evaluations); therefore, a paired *t*-test is used.

(Choice A) The analysis of variance (ANOVA) test compares the mean of ≥3 independent groups, as in a study comparing serum ferritin concentrations (ie, quantitative variable) in children (age 0-17), adults (age 18-59), and seniors (age ≥60).

(Choice B) The chi-square test evaluates the association between 2 categorical variables, as in a study evaluating the association between sex (ie, "male" and "female") and myocardial infarction (ie, presence or absence).

(Choice C) A correlation analysis uses the correlation coefficient to describe the linear relationship between 2 quantitative variables, as in a study evaluating the linear relationship between hours of sleep and irritability score.

(Choice D) Meta-analysis is a statistical technique used to combine and analyze data from several studies to conduct an analysis with a greater statistical power than that of the individual studies.

Educational objective:

The paired *t*-test compares the mean of 2 related groups. The test requires that a quantitative dependent variable (ie, outcome) be evaluated in 2 related (ie, matched, paired) groups.

References

- The differences and similarities between two-sample t-test and paired t-test.

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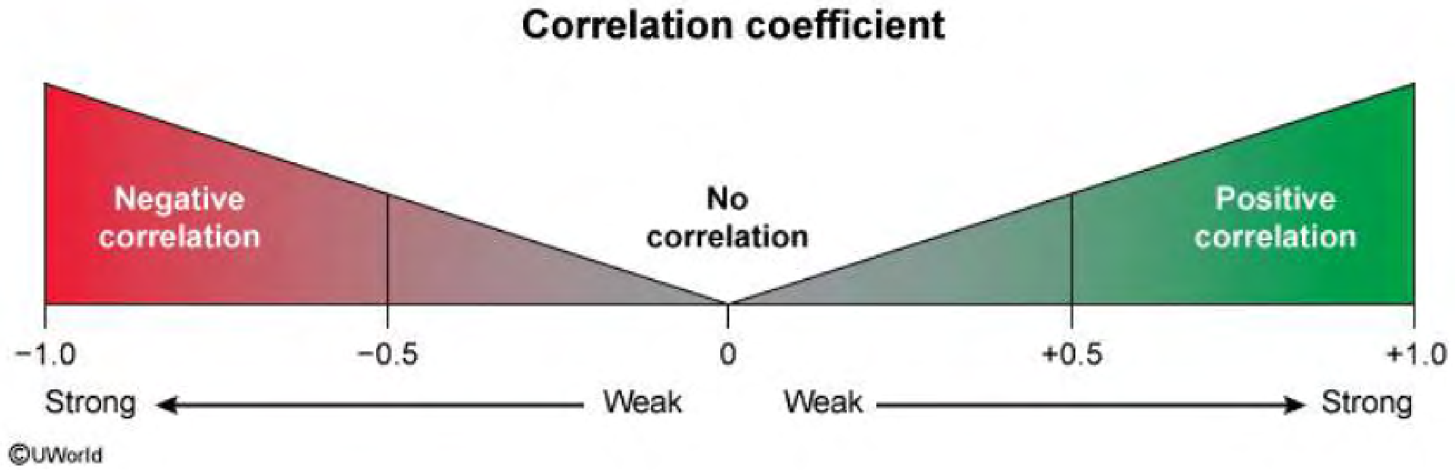
Correlation coefficient
Negative correlation
No correlation
Positive correlation
−1.0
−0.5
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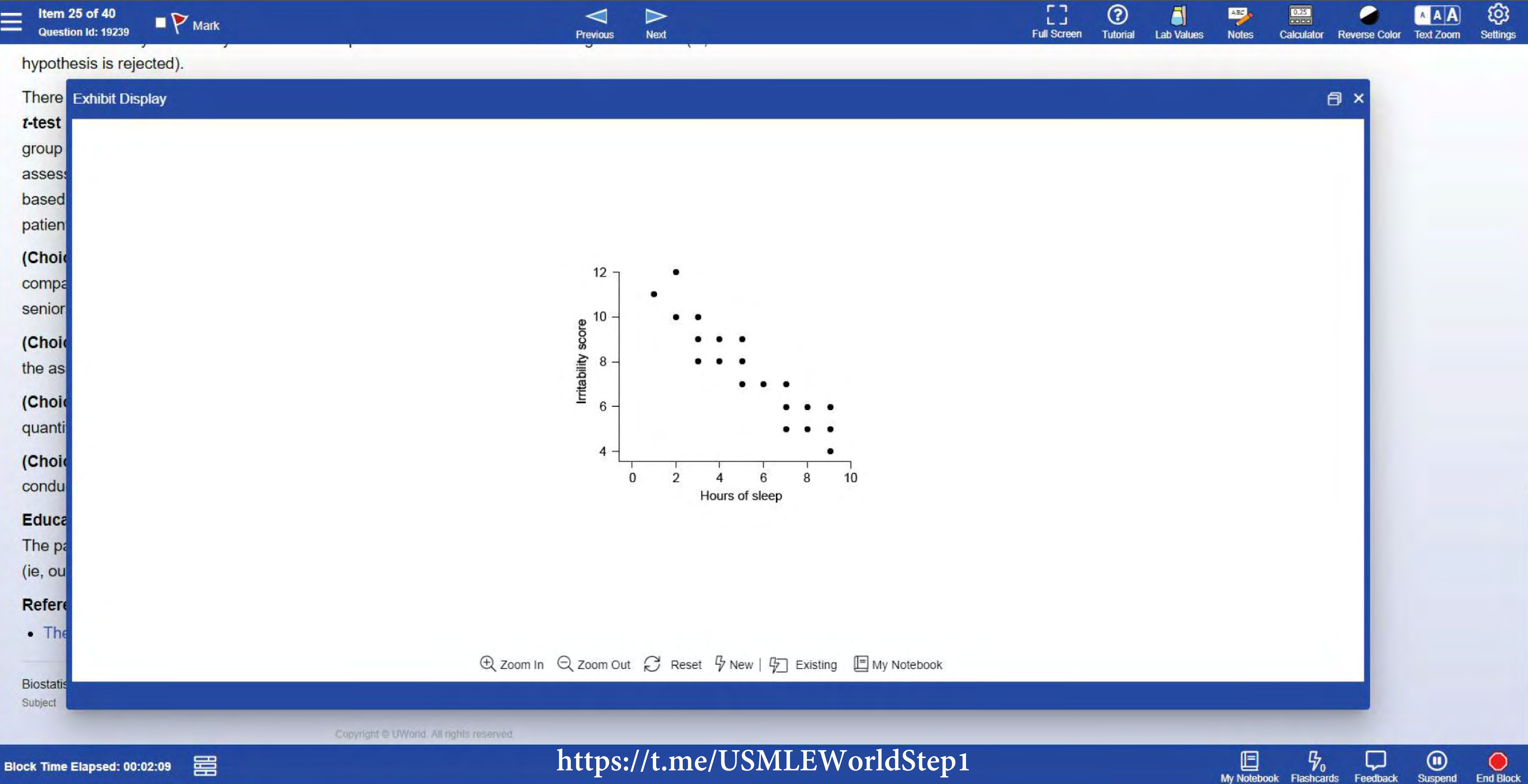
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4
Irritability score
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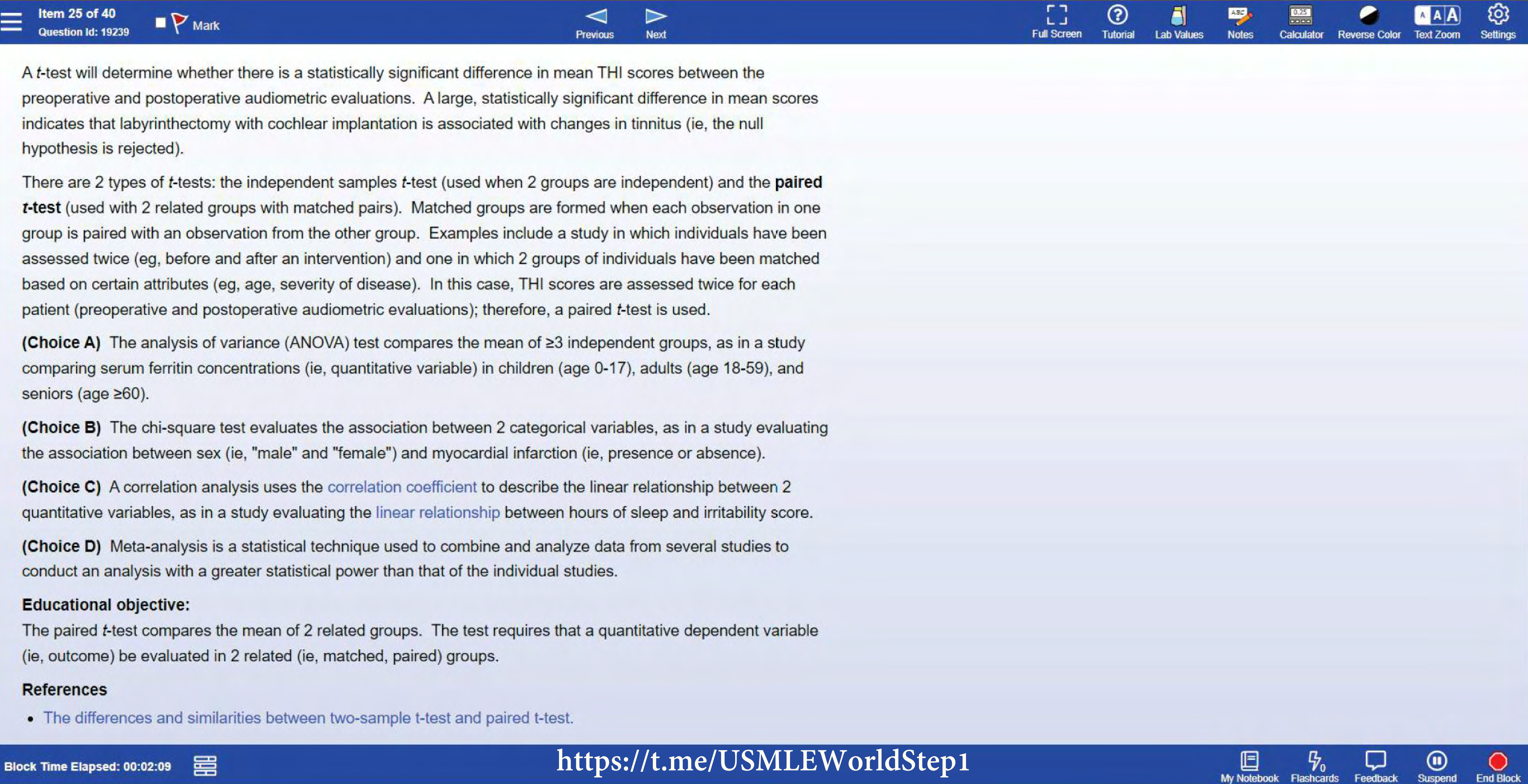

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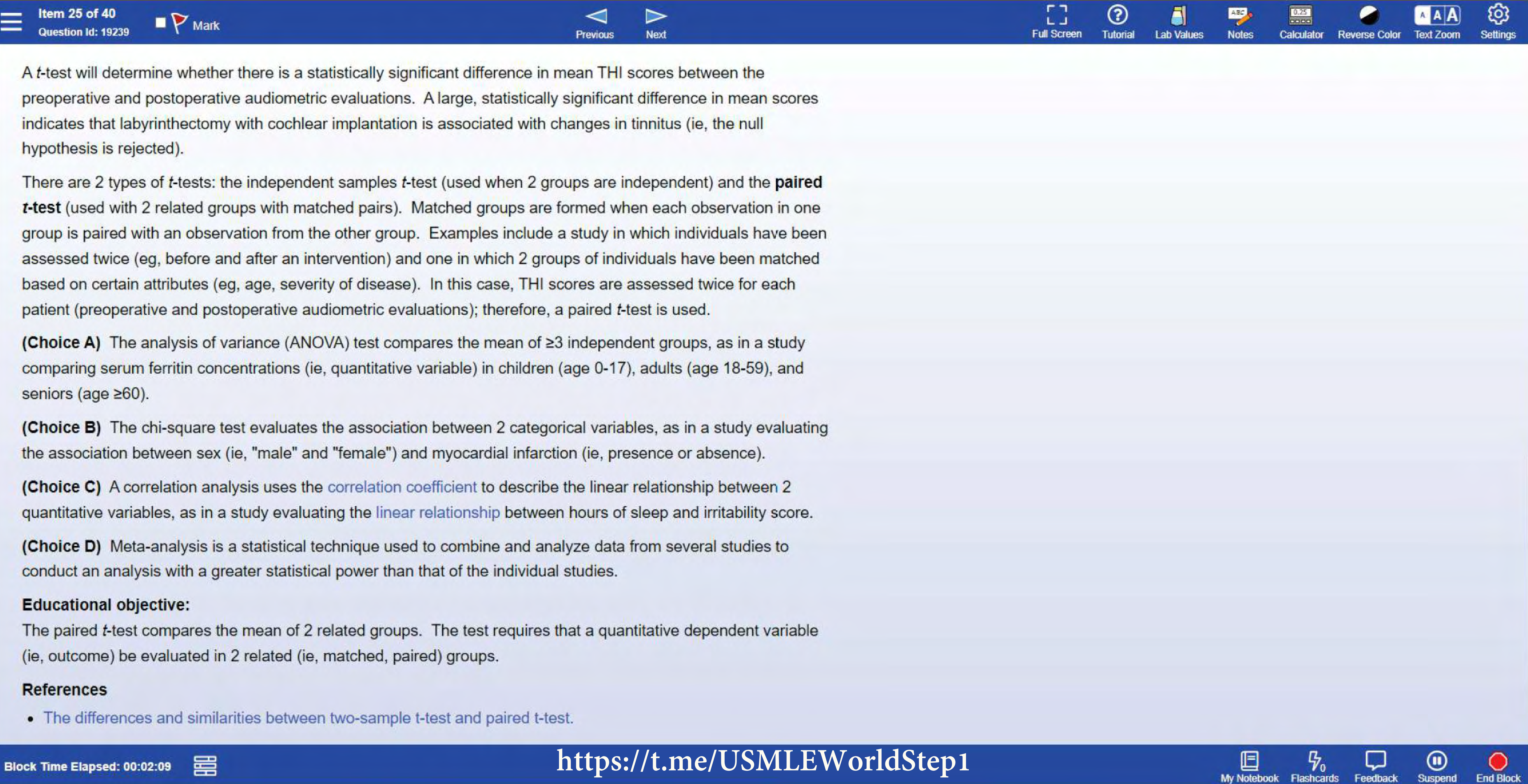
Educational objective:

The paired *t*-test compares the mean of 2 related groups. The test requires that a quantitative dependent variable (ie, outcome) be evaluated in 2 related (ie, matched, paired) groups.

References

- The differences and similarities between two-sample t-test and paired t-test.



A *t*-test will determine whether there is a statistically significant difference in mean THI scores between the preoperative and postoperative audiometric evaluations. A large, statistically significant difference in mean scores indicates that labyrinthectomy with cochlear implantation is associated with changes in tinnitus (ie, the null hypothesis is rejected).

There are 2 types of *t*-tests: the independent samples *t*-test (used when 2 groups are independent) and the **paired *t*-test** (used with 2 related groups with matched pairs). Matched groups are formed when each observation in one group is paired with an observation from the other group. Examples include a study in which individuals have been assessed twice (eg, before and after an intervention) and one in which 2 groups of individuals have been matched based on certain attributes (eg, age, severity of disease). In this case, THI scores are assessed twice for each patient (preoperative and postoperative audiometric evaluations); therefore, a paired *t*-test is used.

(Choice A) The analysis of variance (ANOVA) test compares the mean of ≥3 independent groups, as in a study comparing serum ferritin concentrations (ie, quantitative variable) in children (age 0-17), adults (age 18-59), and seniors (age ≥60).

(Choice B) The chi-square test evaluates the association between 2 categorical variables, as in a study evaluating the association between sex (ie, "male" and "female") and myocardial infarction (ie, presence or absence).

(Choice C) A correlation analysis uses the correlation coefficient to describe the linear relationship between 2 quantitative variables, as in a study evaluating the linear relationship between hours of sleep and irritability score.

(Choice D) Meta-analysis is a statistical technique used to combine and analyze data from several studies to conduct an analysis with a greater statistical power than that of the individual studies.

Educational objective:

The paired *t*-test compares the mean of 2 related groups. The test requires that a quantitative dependent variable (ie, outcome) be evaluated in 2 related (ie, matched, paired) groups.

References

- The differences and similarities between two-sample t-test and paired t-test.

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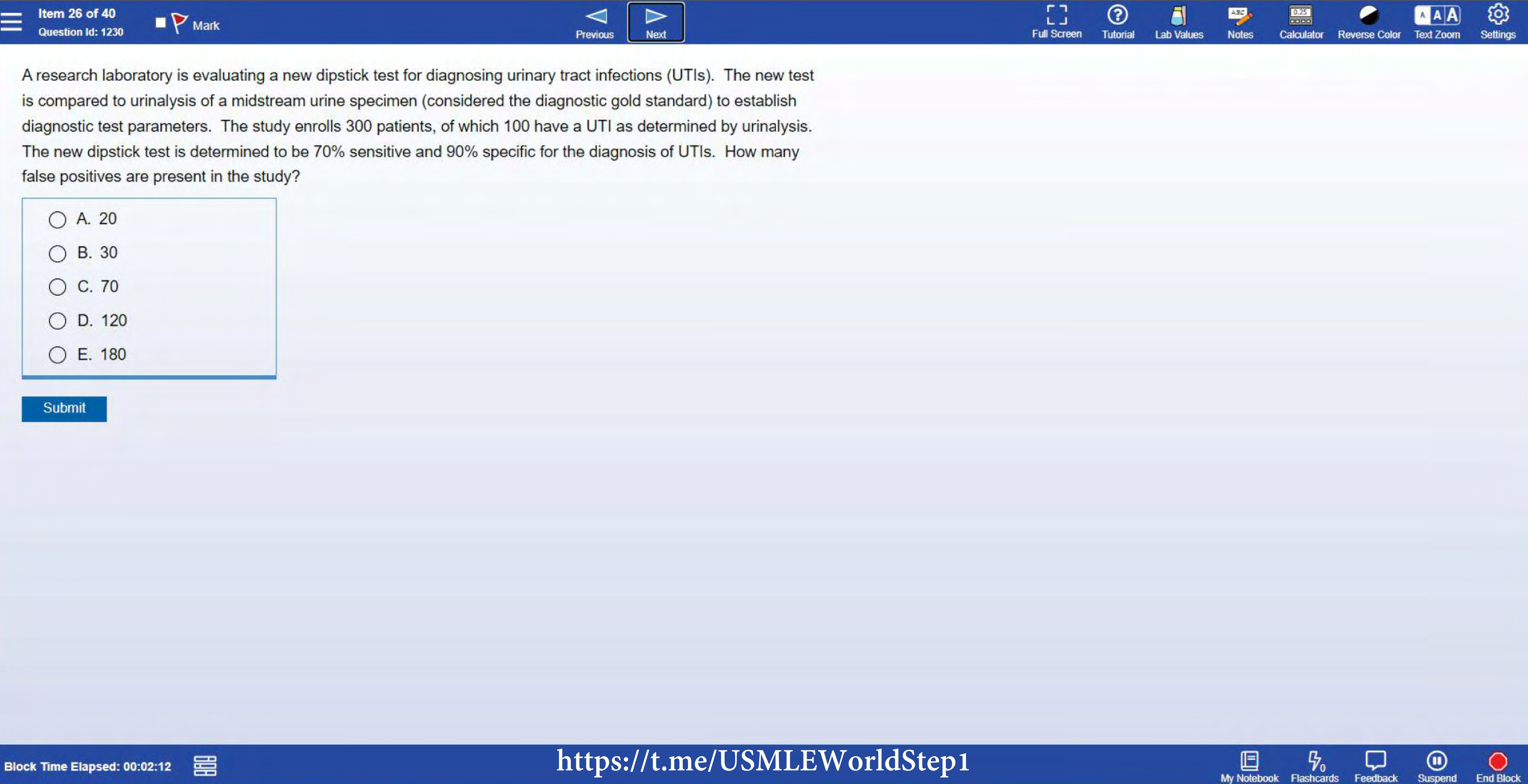
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A research laboratory is evaluating a new dipstick test for diagnosing urinary tract infections (UTIs). The new test is compared to urinalysis of a midstream urine specimen (considered the diagnostic gold standard) to establish diagnostic test parameters. The study enrolls 300 patients, of which 100 have a UTI as determined by urinalysis. The new dipstick test is determined to be 70% sensitive and 90% specific for the diagnosis of UTIs. How many false positives are present in the study?

○ A. 20
○ B. 30
○ C. 70
○ D. 120
○ E. 180

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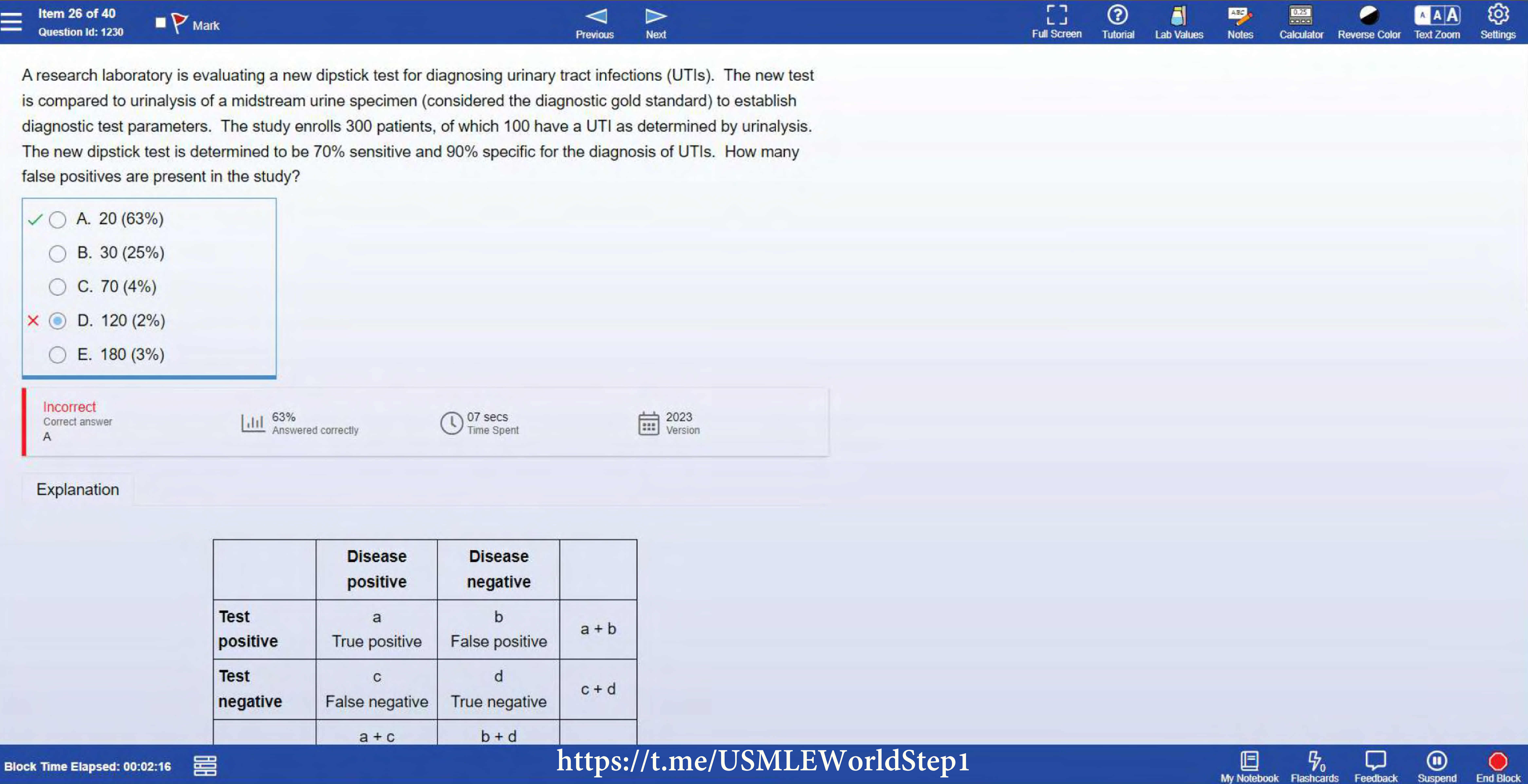
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✓ ○ A. 20 (63%)

○ B. 30 (25%)

○ C. 70 (4%)

✗ ● D. 120 (2%)

○ E. 180 (3%)

Incorrect
Correct answer
A

63%
Answered correctly

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Explanation

	Disease positive	Disease negative	
Test positive	a True positive	b False positive	a + b
Test negative	c False negative	d True negative	c + d
	a + c	b + d	

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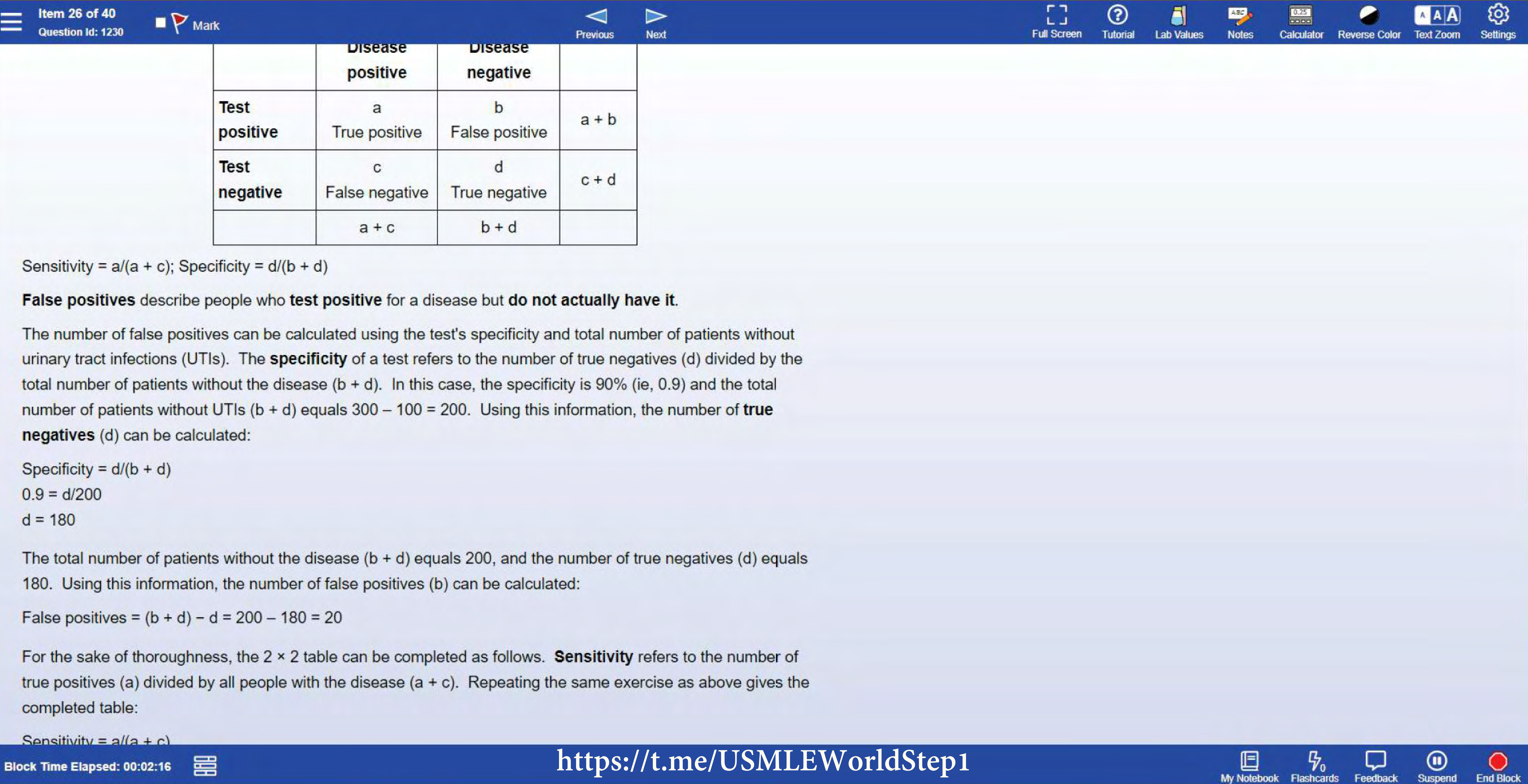
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	Disease positive	Disease negative	
Test positive	a True positive	b False positive	a + b
Test negative	c False negative	d True negative	c + d
	a + c	b + d	

Sensitivity = a/(a + c); Specificity = d/(b + d)

False positives describe people who **test positive** for a disease but **do not actually have it**.

The number of false positives can be calculated using the test's specificity and total number of patients without urinary tract infections (UTIs). The **specificity** of a test refers to the number of true negatives (d) divided by the total number of patients without the disease (b + d). In this case, the specificity is 90% (ie, 0.9) and the total number of patients without UTIs (b + d) equals 300 – 100 = 200. Using this information, the number of **true negatives** (d) can be calculated:

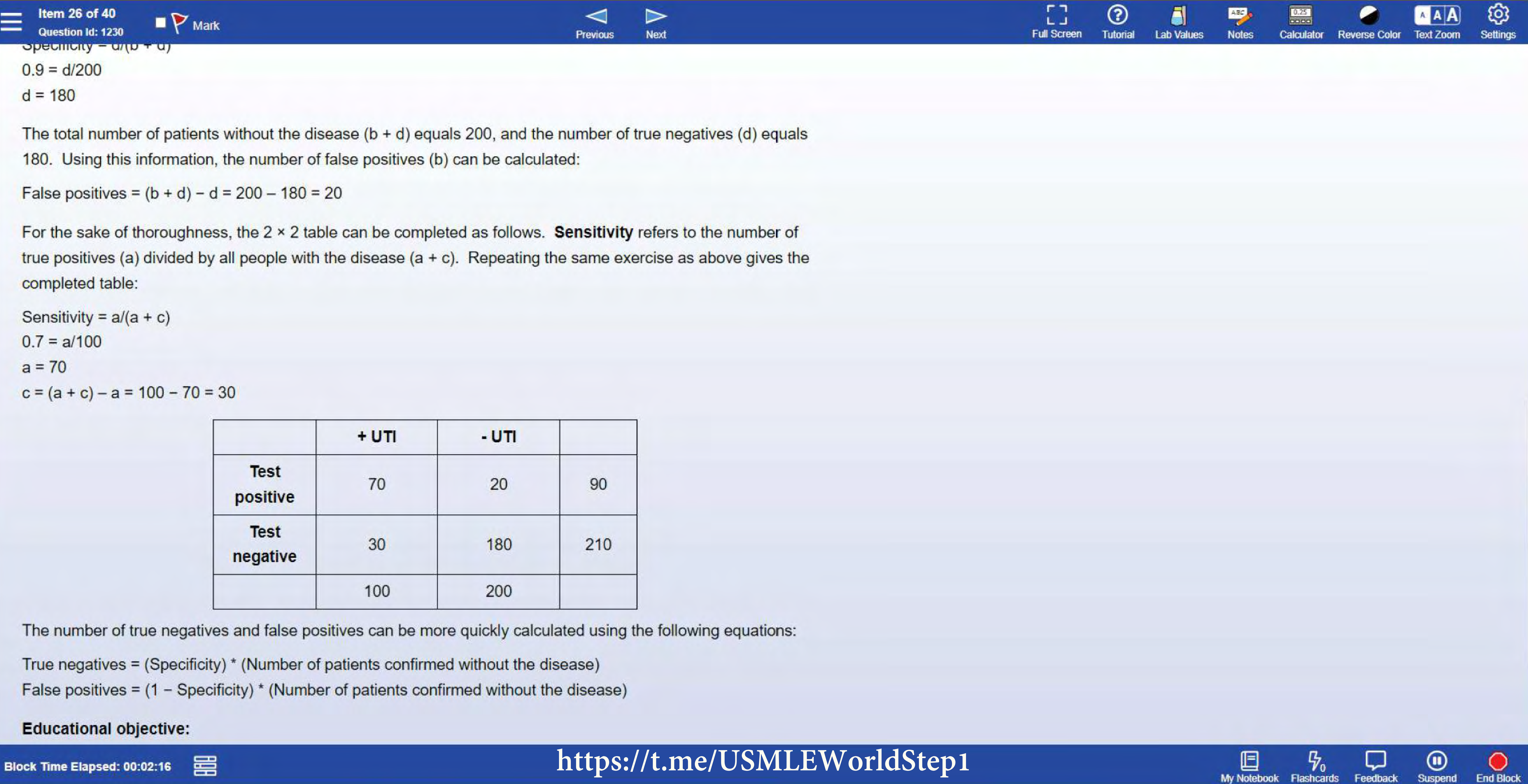
Specificity = d/(b + d)
0.9 = d/200
d = 180

The total number of patients without the disease (b + d) equals 200, and the number of true negatives (d) equals 180. Using this information, the number of false positives (b) can be calculated:

False positives = (b + d) – d = 200 – 180 = 20

For the sake of thoroughness, the 2 × 2 table can be completed as follows. **Sensitivity** refers to the number of true positives (a) divided by all people with the disease (a + c). Repeating the same exercise as above gives the completed table:

Sensitivity = a/(a + c)



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The total number of patients without the disease (b + d) equals 200, and the number of true negatives (d) equals 180. Using this information, the number of false positives (b) can be calculated:

False positives = (b + d) – d = 200 – 180 = 20

For the sake of thoroughness, the 2 × 2 table can be completed as follows. **Sensitivity** refers to the number of true positives (a) divided by all people with the disease (a + c). Repeating the same exercise as above gives the completed table:

Sensitivity = a/(a + c)
0.7 = a/100
a = 70
c = (a + c) – a = 100 – 70 = 30

	+ UTI	**- UTI**	
Test positive	70	20	90
Test negative	30	180	210
	100	200	

The number of true negatives and false positives can be more quickly calculated using the following equations:

True negatives = (Specificity) * (Number of patients confirmed without the disease)
False positives = (1 – Specificity) * (Number of patients confirmed without the disease)

Educational objective:

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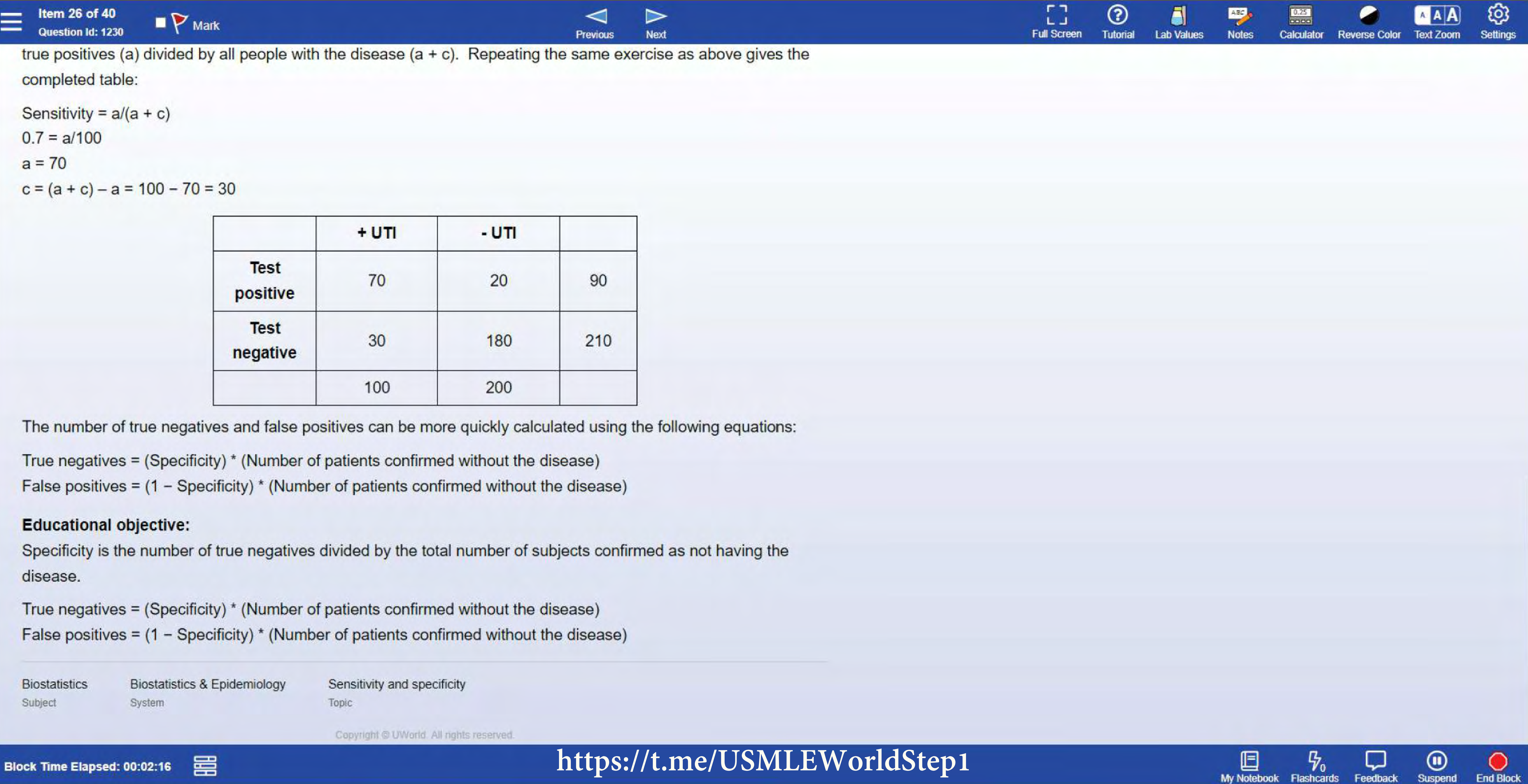
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Educational objective:
Specificity is the number of true negatives divided by the total number of subjects confirmed as not having the disease.

True negatives = (Specificity) * (Number of patients confirmed without the disease)
False positives = (1 – Specificity) * (Number of patients confirmed without the disease)

Biostatistics	Biostatistics & Epidemiology	Sensitivity and specificity
Subject	System	Topic

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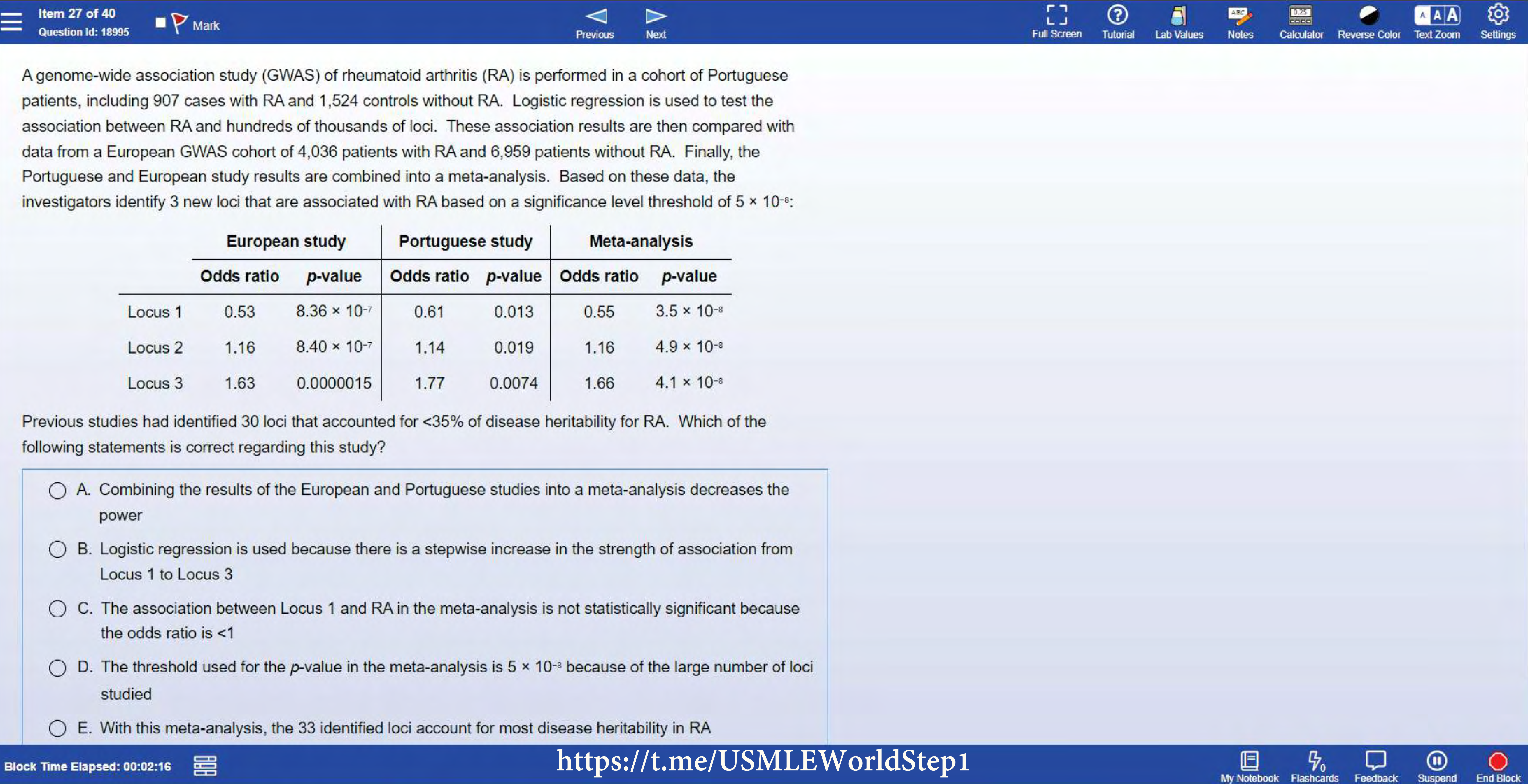
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A genome-wide association study (GWAS) of rheumatoid arthritis (RA) is performed in a cohort of Portuguese patients, including 907 cases with RA and 1,524 controls without RA. Logistic regression is used to test the association between RA and hundreds of thousands of loci. These association results are then compared with data from a European GWAS cohort of 4,036 patients with RA and 6,959 patients without RA. Finally, the Portuguese and European study results are combined into a meta-analysis. Based on these data, the investigators identify 3 new loci that are associated with RA based on a significance level threshold of 5×10^{-8}:

	European study		**Portuguese study**		**Meta-analysis**	
	Odds ratio	***p*-value**	**Odds ratio**	***p*-value**	**Odds ratio**	***p*-value**
Locus 1	0.53	8.36×10^{-7}	0.61	0.013	0.55	3.5×10^{-8}
Locus 2	1.16	8.40×10^{-7}	1.14	0.019	1.16	4.9×10^{-8}
Locus 3	1.63	0.0000015	1.77	0.0074	1.66	4.1×10^{-8}

Previous studies had identified 30 loci that accounted for <35% of disease heritability for RA. Which of the following statements is correct regarding this study?

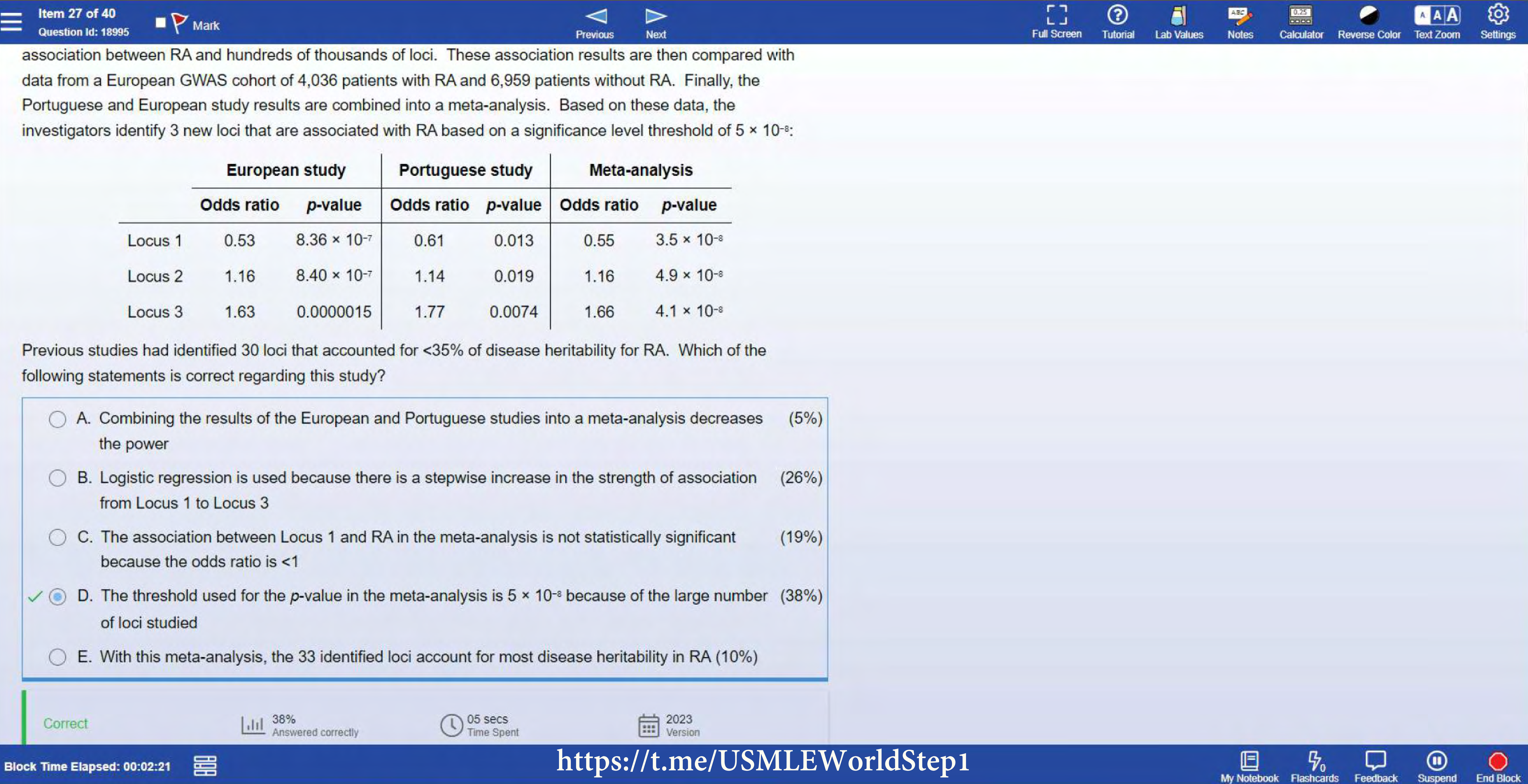
○ A. Combining the results of the European and Portuguese studies into a meta-analysis decreases the power

○ B. Logistic regression is used because there is a stepwise increase in the strength of association from Locus 1 to Locus 3

○ C. The association between Locus 1 and RA in the meta-analysis is not statistically significant because the odds ratio is <1

○ D. The threshold used for the *p*-value in the meta-analysis is 5×10^{-8} because of the large number of loci studied

○ E. With this meta-analysis, the 33 identified loci account for most disease heritability in RA



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Previous studies had identified 30 loci that accounted for <35% of disease heritability for RA. Which of the following statements is correct regarding this study?

○ A. Combining the results of the European and Portuguese studies into a meta-analysis decreases the power (5%)

○ B. Logistic regression is used because there is a stepwise increase in the strength of association from Locus 1 to Locus 3 (26%)

○ C. The association between Locus 1 and RA in the meta-analysis is not statistically significant because the odds ratio is <1 (19%)

✓ ● D. The threshold used for the *p*-value in the meta-analysis is 5×10^{-8} because of the large number of loci studied (38%)

○ E. With this meta-analysis, the 33 identified loci account for most disease heritability in RA (10%)

Correct

38% Answered correctly

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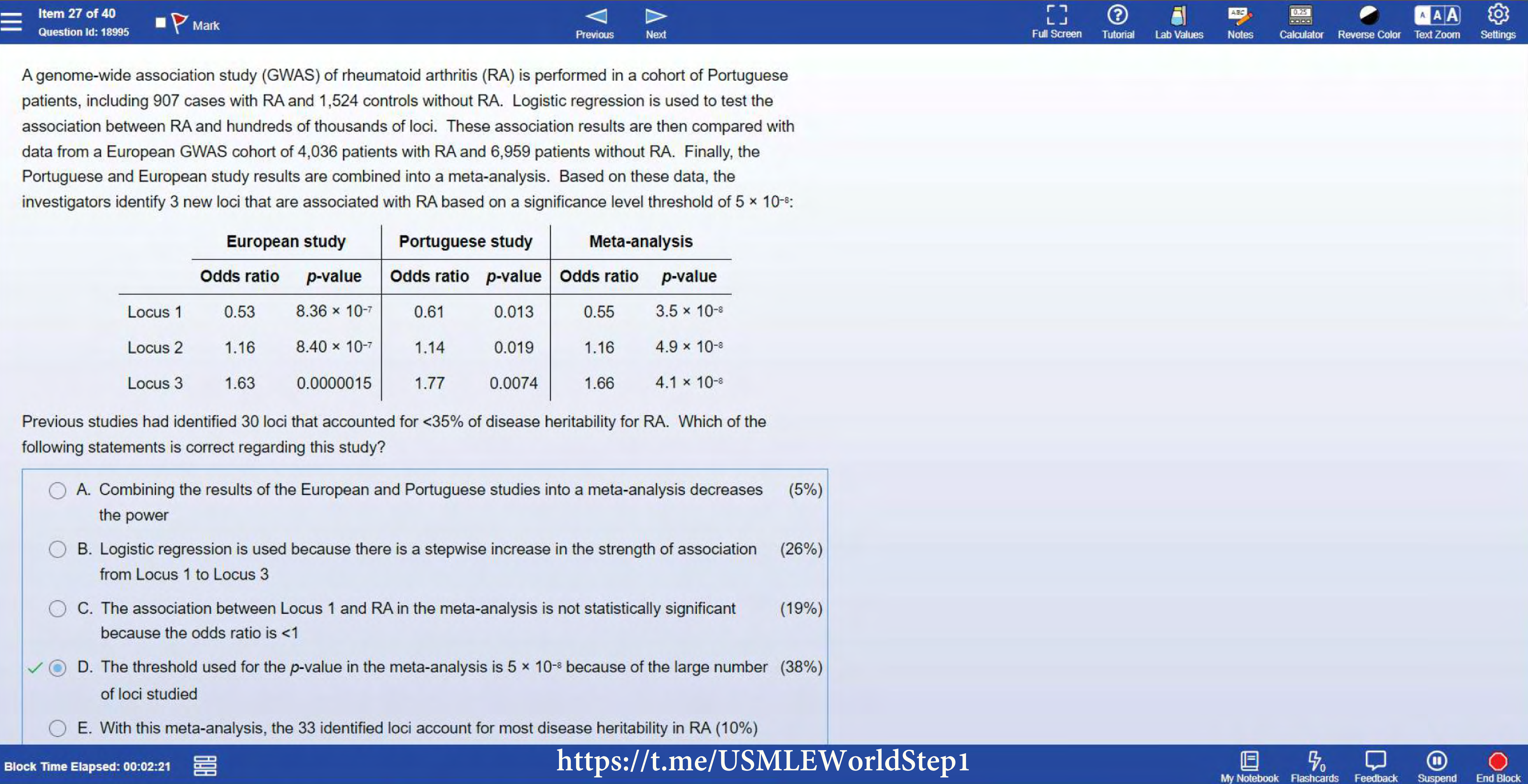
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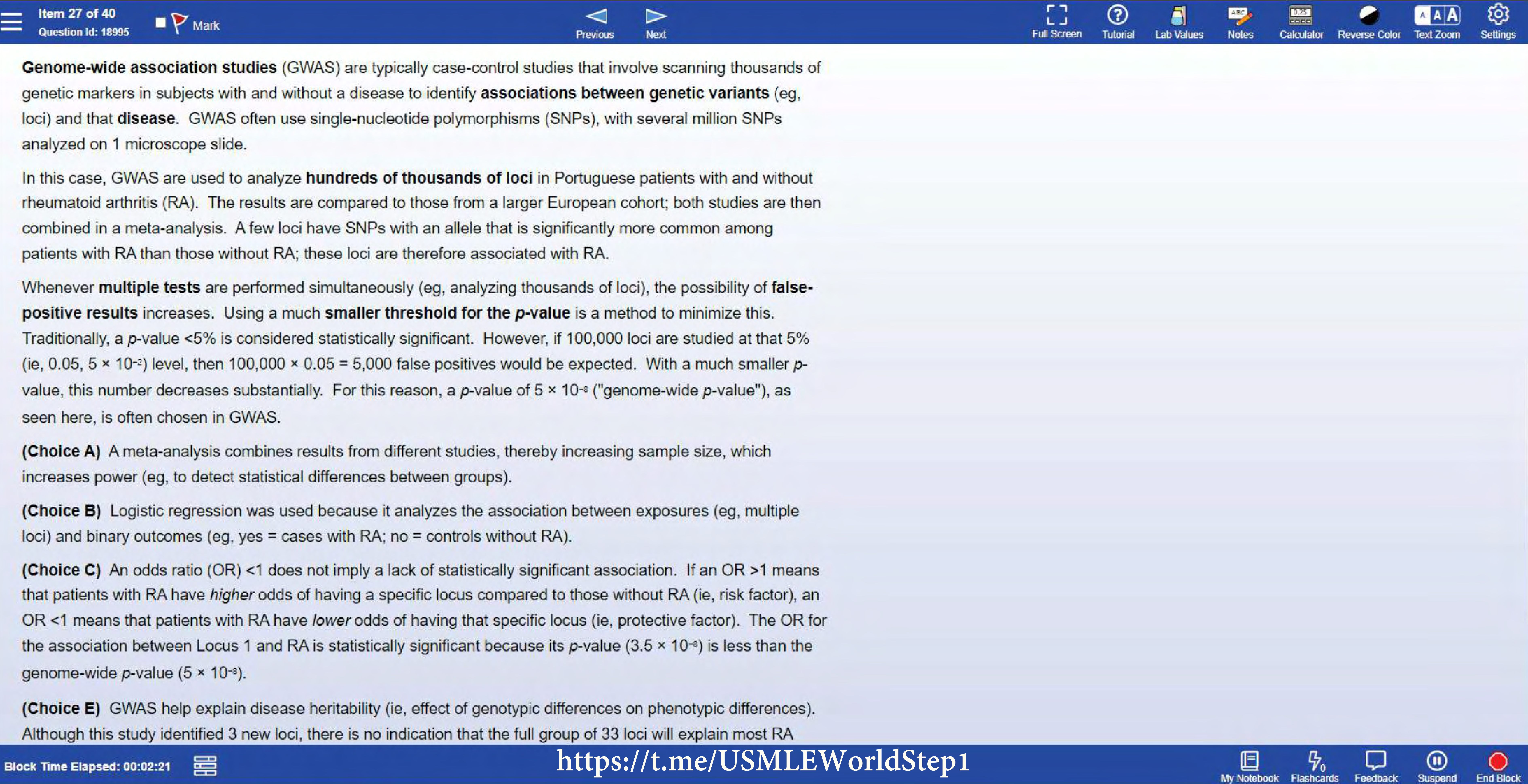


Genome-wide association studies (GWAS) are typically case-control studies that involve scanning thousands of genetic markers in subjects with and without a disease to identify **associations between genetic variants** (eg, loci) and that **disease**. GWAS often use single-nucleotide polymorphisms (SNPs), with several million SNPs analyzed on 1 microscope slide.

In this case, GWAS are used to analyze **hundreds of thousands of loci** in Portuguese patients with and without rheumatoid arthritis (RA). The results are compared to those from a larger European cohort; both studies are then combined in a meta-analysis. A few loci have SNPs with an allele that is significantly more common among patients with RA than those without RA; these loci are therefore associated with RA.

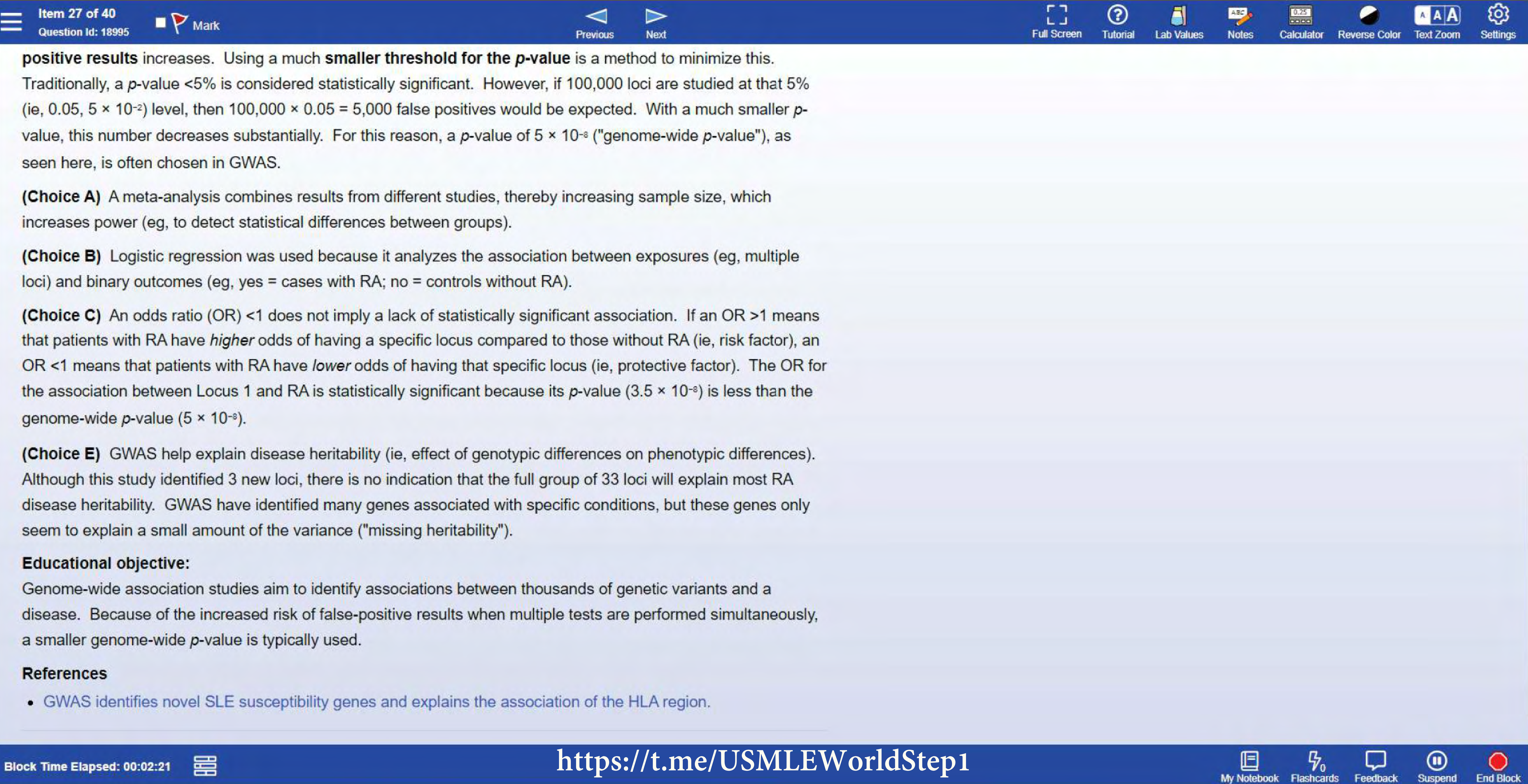
Whenever **multiple tests** are performed simultaneously (eg, analyzing thousands of loci), the possibility of **false-positive results** increases. Using a much **smaller threshold for the *p*-value** is a method to minimize this. Traditionally, a *p*-value <5% is considered statistically significant. However, if 100,000 loci are studied at that 5% (ie, 0.05, 5×10^{-2}) level, then 100,000 × 0.05 = 5,000 false positives would be expected. With a much smaller *p*-value, this number decreases substantially. For this reason, a *p*-value of 5×10^{-8} ("genome-wide *p*-value"), as seen here, is often chosen in GWAS.

(Choice A) A meta-analysis combines results from different studies, thereby increasing sample size, which increases power (eg, to detect statistical differences between groups).

(Choice B) Logistic regression was used because it analyzes the association between exposures (eg, multiple loci) and binary outcomes (eg, yes = cases with RA; no = controls without RA).

(Choice C) An odds ratio (OR) <1 does not imply a lack of statistically significant association. If an OR >1 means that patients with RA have *higher* odds of having a specific locus compared to those without RA (ie, risk factor), an OR <1 means that patients with RA have *lower* odds of having that specific locus (ie, protective factor). The OR for the association between Locus 1 and RA is statistically significant because its *p*-value (3.5×10^{-8}) is less than the genome-wide *p*-value (5×10^{-8}).

(Choice E) GWAS help explain disease heritability (ie, effect of genotypic differences on phenotypic differences). Although this study identified 3 new loci, there is no indication that the full group of 33 loci will explain most RA



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(Choice E) GWAS help explain disease heritability (ie, effect of genotypic differences on phenotypic differences). Although this study identified 3 new loci, there is no indication that the full group of 33 loci will explain most RA disease heritability. GWAS have identified many genes associated with specific conditions, but these genes only seem to explain a small amount of the variance ("missing heritability").

Educational objective:

Genome-wide association studies aim to identify associations between thousands of genetic variants and a disease. Because of the increased risk of false-positive results when multiple tests are performed simultaneously, a smaller genome-wide *p*-value is typically used.

References

- GWAS identifies novel SLE susceptibility genes and explains the association of the HLA region.

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A geneticist is interested in the potential causes of a congenital abnormality. She hypothesizes that acetaminophen use during the first trimester of pregnancy might be associated with the abnormality. In her study, a sample of mothers of children with and without the abnormality are randomly selected from government birth records. Personal interviews are then conducted with the mothers to determine fetal exposure to acetaminophen. Results show that mothers of children who do not have the abnormality did not take acetaminophen as frequently during the first trimester. This type of study is most susceptible to which of the following types of bias?

○ A. Allocation bias
○ B. Detection bias
○ C. Recall bias
○ D. Referral bias
○ E. Selection bias

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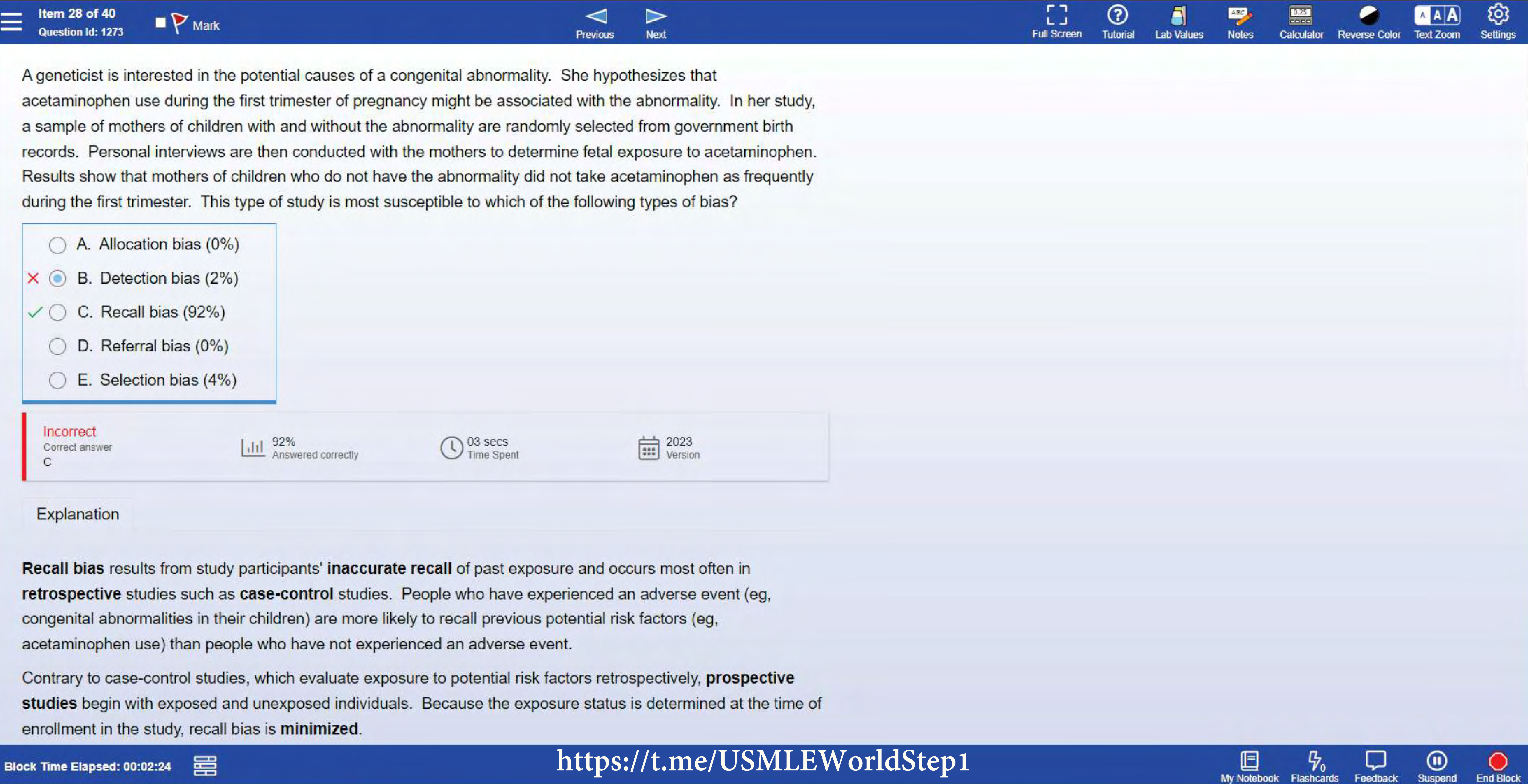
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- ○ A. Allocation bias (0%)
- ✗ ● B. Detection bias (2%)
- ✓ ○ C. Recall bias (92%)
- ○ D. Referral bias (0%)
- ○ E. Selection bias (4%)

Incorrect
Correct answer
C

92%
Answered correctly

03 secs
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Explanation

Recall bias results from study participants' **inaccurate recall** of past exposure and occurs most often in **retrospective** studies such as **case-control** studies. People who have experienced an adverse event (eg, congenital abnormalities in their children) are more likely to recall previous potential risk factors (eg, acetaminophen use) than people who have not experienced an adverse event.

Contrary to case-control studies, which evaluate exposure to potential risk factors retrospectively, **prospective studies** begin with exposed and unexposed individuals. Because the exposure status is determined at the time of enrollment in the study, recall bias is **minimized**.

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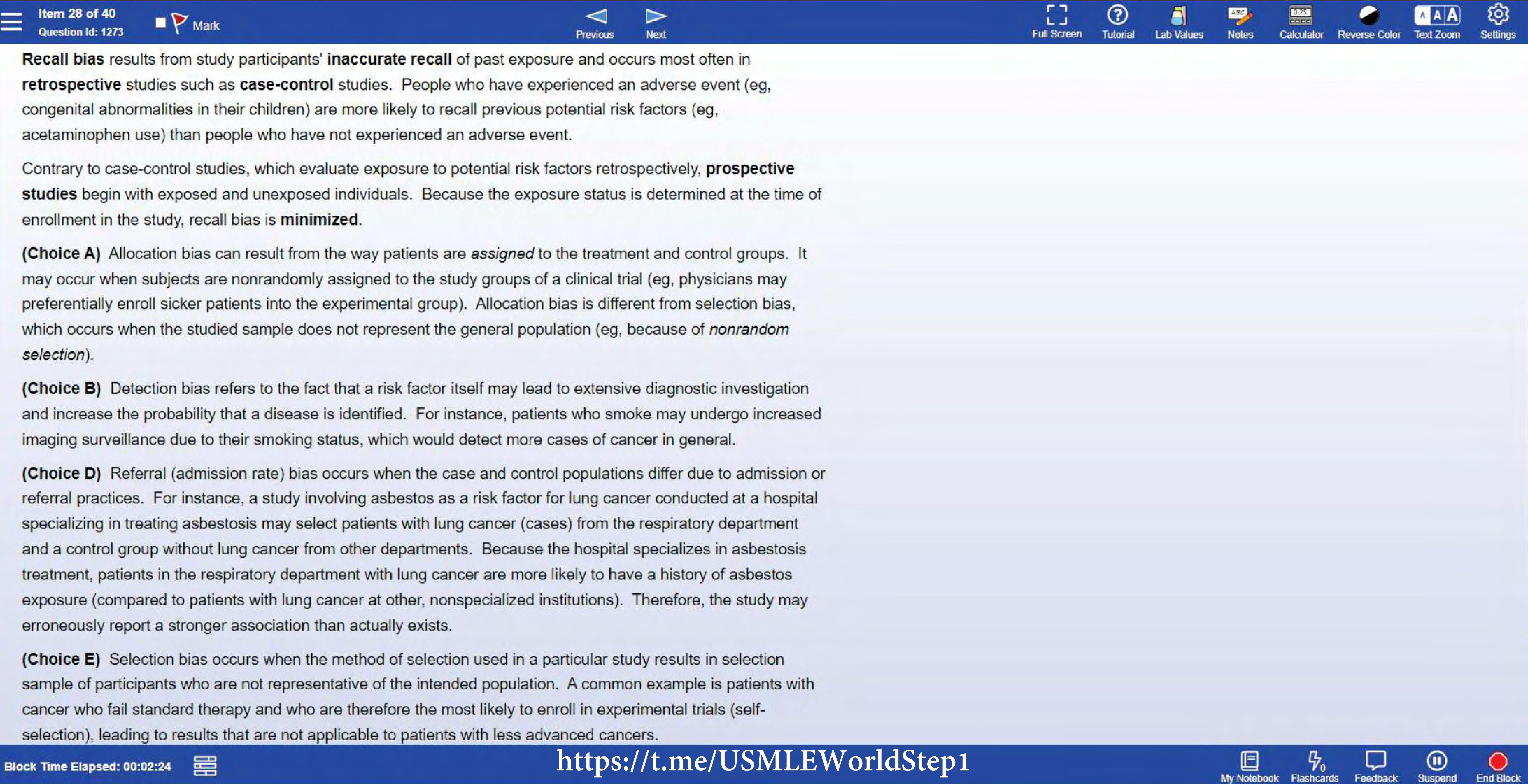

Recall bias results from study participants' **inaccurate recall** of past exposure and occurs most often in **retrospective** studies such as **case-control** studies. People who have experienced an adverse event (eg, congenital abnormalities in their children) are more likely to recall previous potential risk factors (eg, acetaminophen use) than people who have not experienced an adverse event.

Contrary to case-control studies, which evaluate exposure to potential risk factors retrospectively, **prospective studies** begin with exposed and unexposed individuals. Because the exposure status is determined at the time of enrollment in the study, recall bias is **minimized**.

(Choice A) Allocation bias can result from the way patients are *assigned* to the treatment and control groups. It may occur when subjects are nonrandomly assigned to the study groups of a clinical trial (eg, physicians may preferentially enroll sicker patients into the experimental group). Allocation bias is different from selection bias, which occurs when the studied sample does not represent the general population (eg, because of *nonrandom selection*).

(Choice B) Detection bias refers to the fact that a risk factor itself may lead to extensive diagnostic investigation and increase the probability that a disease is identified. For instance, patients who smoke may undergo increased imaging surveillance due to their smoking status, which would detect more cases of cancer in general.

(Choice D) Referral (admission rate) bias occurs when the case and control populations differ due to admission or referral practices. For instance, a study involving asbestos as a risk factor for lung cancer conducted at a hospital specializing in treating asbestosis may select patients with lung cancer (cases) from the respiratory department and a control group without lung cancer from other departments. Because the hospital specializes in asbestosis treatment, patients in the respiratory department with lung cancer are more likely to have a history of asbestos exposure (compared to patients with lung cancer at other, nonspecialized institutions). Therefore, the study may erroneously report a stronger association than actually exists.

(Choice E) Selection bias occurs when the method of selection used in a particular study results in selection sample of participants who are not representative of the intended population. A common example is patients with cancer who fail standard therapy and who are therefore the most likely to enroll in experimental trials (self-selection), leading to results that are not applicable to patients with less advanced cancers.

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Educational objective:

Recall bias results from study participants' inaccurate recall of past exposure and occurs most often in retrospective studies such as case-control studies. People who have experienced an adverse event are more likely to recall risk factors than those who have not experienced an adverse event.

Biostatistics	Biostatistics & Epidemiology	Bias
Subject	System	Topic

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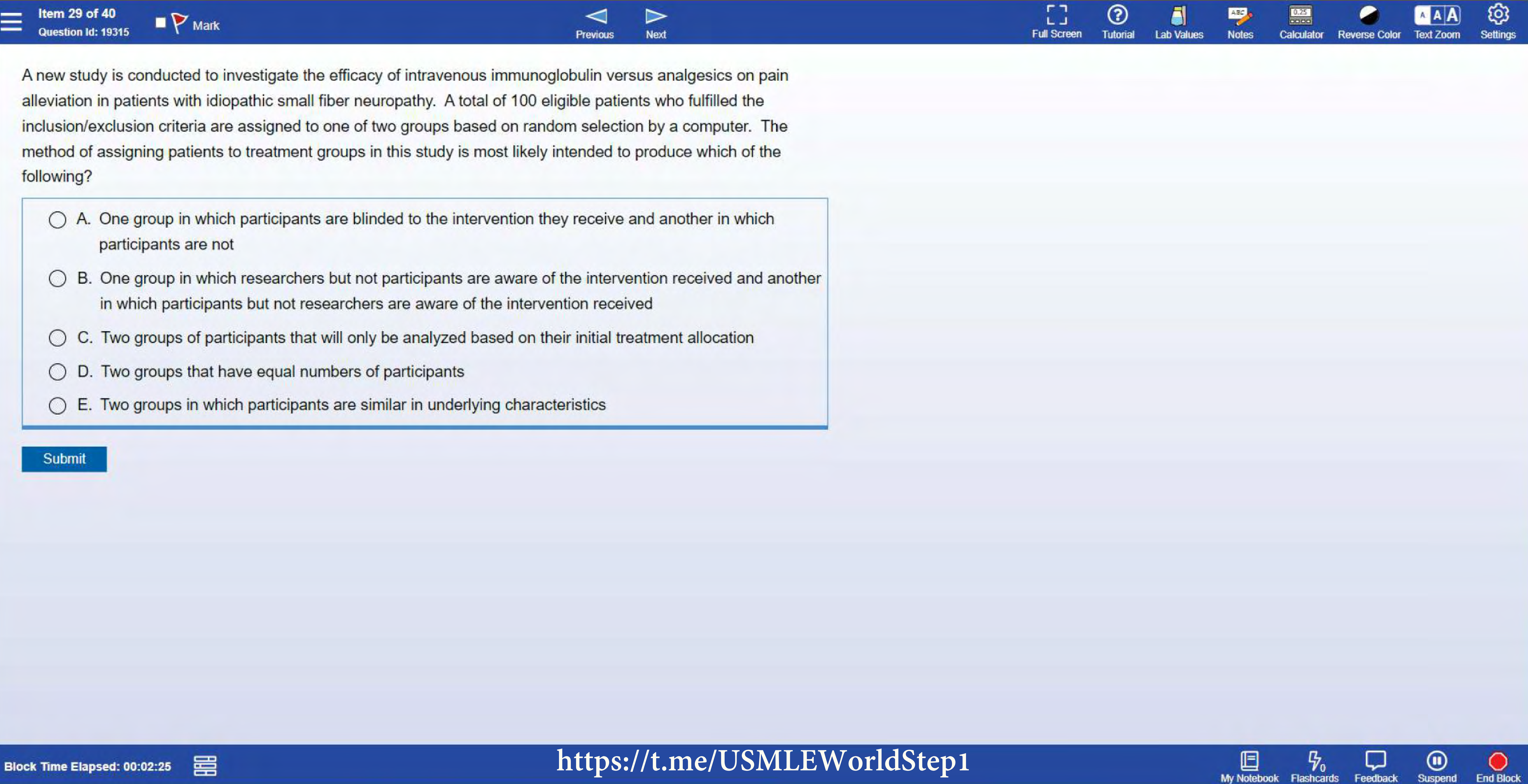
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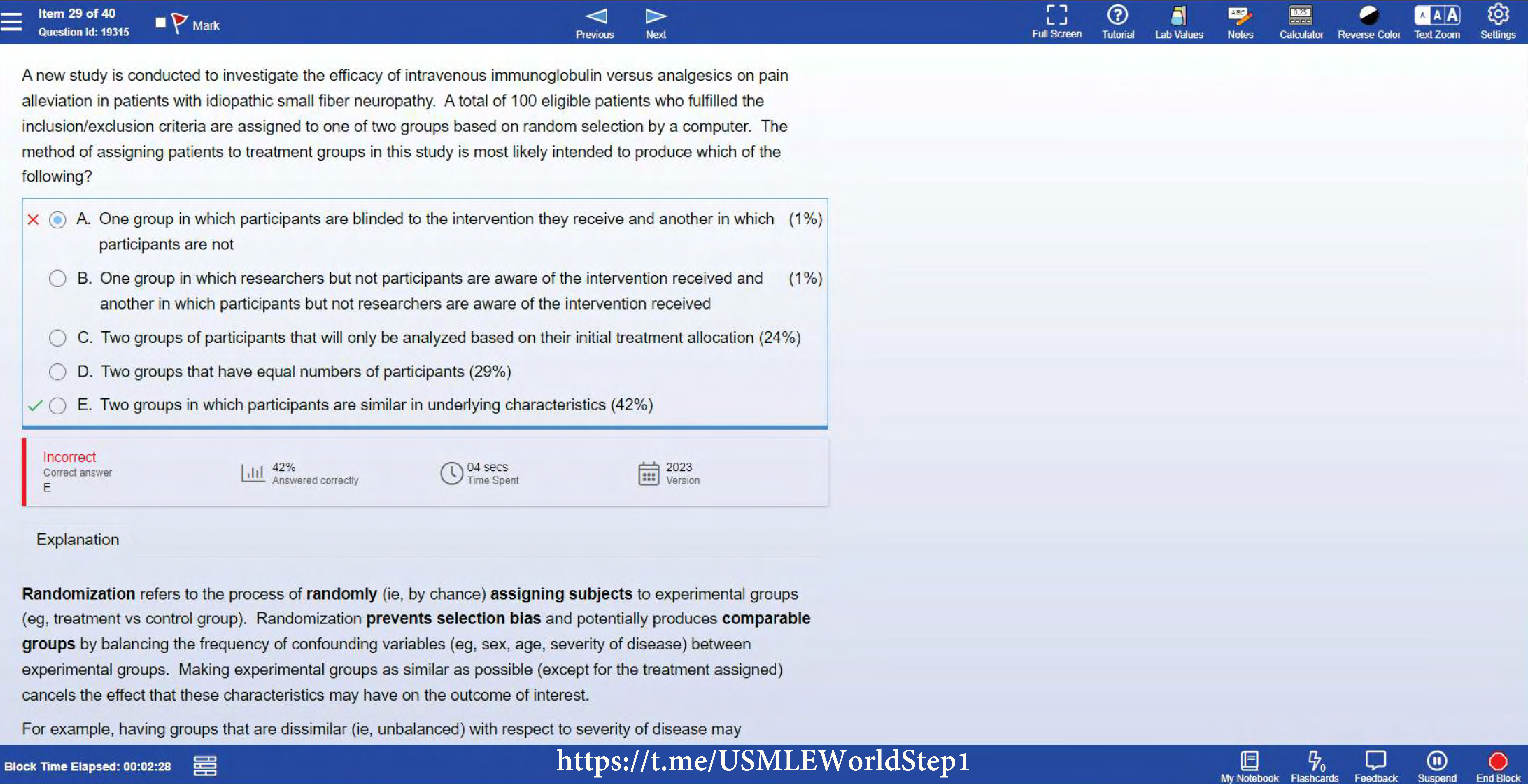
A new study is conducted to investigate the efficacy of intravenous immunoglobulin versus analgesics on pain alleviation in patients with idiopathic small fiber neuropathy. A total of 100 eligible patients who fulfilled the inclusion/exclusion criteria are assigned to one of two groups based on random selection by a computer. The method of assigning patients to treatment groups in this study is most likely intended to produce which of the following?

- ○ A. One group in which participants are blinded to the intervention they receive and another in which participants are not
- ○ B. One group in which researchers but not participants are aware of the intervention received and another in which participants but not researchers are aware of the intervention received
- ○ C. Two groups of participants that will only be analyzed based on their initial treatment allocation
- ○ D. Two groups that have equal numbers of participants
- ○ E. Two groups in which participants are similar in underlying characteristics



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- ✗ ● A. One group in which participants are blinded to the intervention they receive and another in which participants are not (1%)
- ○ B. One group in which researchers but not participants are aware of the intervention received and another in which participants but not researchers are aware of the intervention received (1%)
- ○ C. Two groups of participants that will only be analyzed based on their initial treatment allocation (24%)
- ○ D. Two groups that have equal numbers of participants (29%)
- ✓ ○ E. Two groups in which participants are similar in underlying characteristics (42%)

Incorrect
Correct answer
E

42%
Answered correctly

04 secs
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Explanation

Randomization refers to the process of **randomly** (ie, by chance) **assigning subjects** to experimental groups (eg, treatment vs control group). Randomization **prevents selection bias** and potentially produces **comparable groups** by balancing the frequency of confounding variables (eg, sex, age, severity of disease) between experimental groups. Making experimental groups as similar as possible (except for the treatment assigned) cancels the effect that these characteristics may have on the outcome of interest.

For example, having groups that are dissimilar (ie, unbalanced) with respect to severity of disease may

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Randomization refers to the process of **randomly** (ie, by chance) **assigning subjects** to experimental groups (eg, treatment vs control group). Randomization **prevents selection bias** and potentially produces **comparable groups** by balancing the frequency of confounding variables (eg, sex, age, severity of disease) between experimental groups. Making experimental groups as similar as possible (except for the treatment assigned) cancels the effect that these characteristics may have on the outcome of interest.

For example, having groups that are dissimilar (ie, unbalanced) with respect to severity of disease may underestimate or overestimate the effect of a treatment, depending on which group has a greater proportion of severe cases. The best way to account for the effects of these variables is to randomly assign subjects to experimental groups. Afterward, the groups are analyzed to ensure that they are statistically similar in underlying variables, with the results often reported in a baseline characteristics table (eg, weight, sex, age).

Therefore, randomization increases the likelihood that any **difference observed between groups is due exclusively to the treatment** and not to other characteristics.

(Choices A and B) A blind study is a type of clinical trial in which either the participants or the researchers (ie, single blind) or both the participants and the researchers (ie, double blind) are unaware of treatment assignments. Although this study used randomization to assign patients to treatment groups, no information is provided regarding the awareness of participants or researchers to treatment assignments. By itself, randomization does not make a study blind.

(Choice C) A study that analyzes all participants as initially allocated after randomization, regardless of what happens during the study period, is using an intention-to-treat (ITT) analysis. ITT is not a result of randomization; instead, it is used to preserve the effect of randomization.

(Choice D) Depending on the randomization method (eg, simple, complete) used to allocate participants into experimental groups, a study may or may not result in groups that are similar in sample size. Regardless, the goal of randomization is not to create groups of similar size (which can be done trivially by alternating group assignment as patients enroll) but rather to make the underlying characteristics of experimental groups as similar as possible.

Educational objective:

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Educational objective:

Randomization refers to the process of using random methods to assign subjects to experimental groups. Its purpose is to make experimental groups as similar as possible (except for the treatment assignment) to ensure that any difference observed between the groups is due exclusively to the treatment and not to other underlying factors.

References

- Randomized allocation to treatment groups and the importance of adjusting for covariates.

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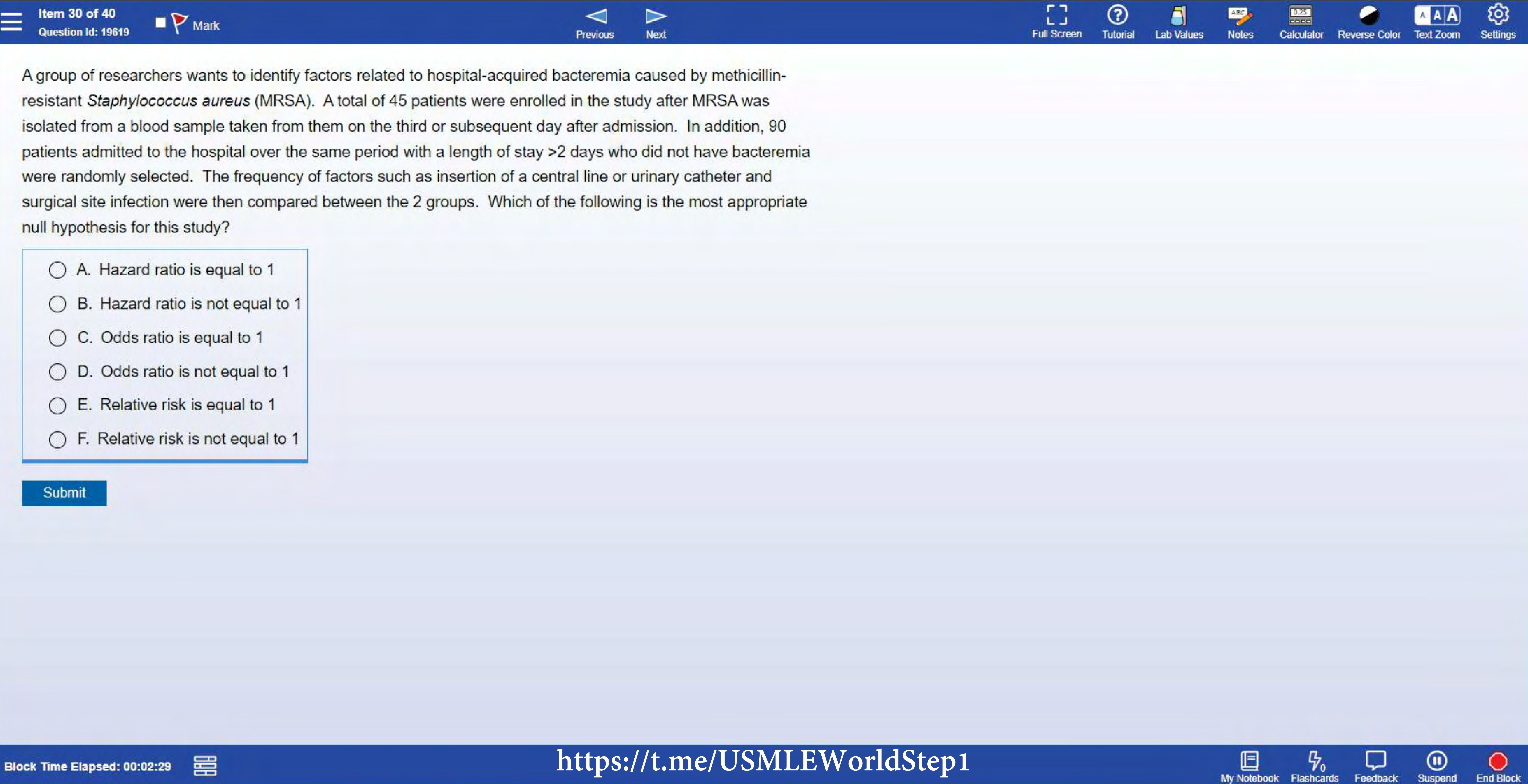
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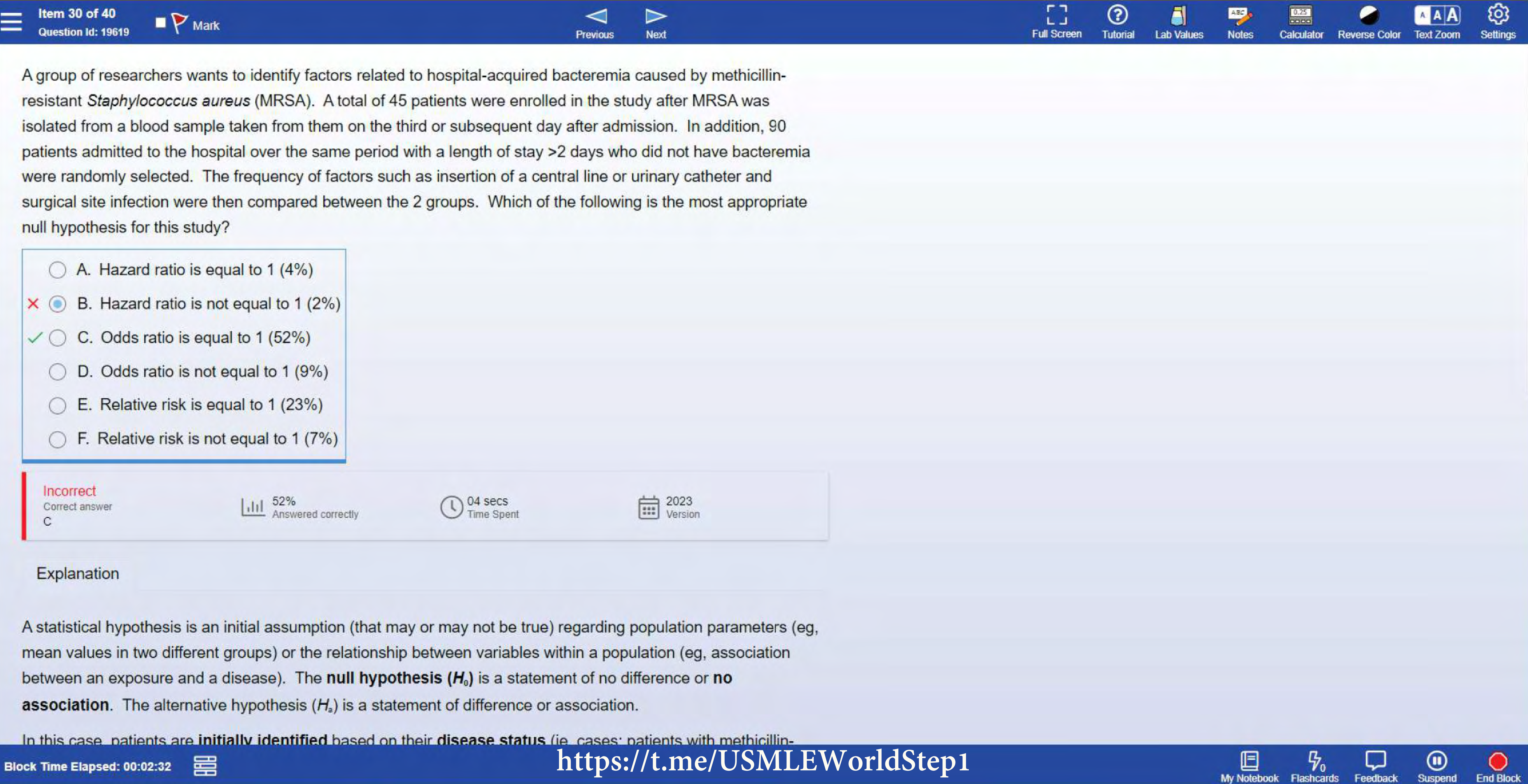
A group of researchers wants to identify factors related to hospital-acquired bacteremia caused by methicillin-resistant *Staphylococcus aureus* (MRSA). A total of 45 patients were enrolled in the study after MRSA was isolated from a blood sample taken from them on the third or subsequent day after admission. In addition, 90 patients admitted to the hospital over the same period with a length of stay >2 days who did not have bacteremia were randomly selected. The frequency of factors such as insertion of a central line or urinary catheter and surgical site infection were then compared between the 2 groups. Which of the following is the most appropriate null hypothesis for this study?

○ A. Hazard ratio is equal to 1
○ B. Hazard ratio is not equal to 1
○ C. Odds ratio is equal to 1
○ D. Odds ratio is not equal to 1
○ E. Relative risk is equal to 1
○ F. Relative risk is not equal to 1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- ○ A. Hazard ratio is equal to 1 (4%)
- ✗ ● B. Hazard ratio is not equal to 1 (2%)
- ✓ ○ C. Odds ratio is equal to 1 (52%)
- ○ D. Odds ratio is not equal to 1 (9%)
- ○ E. Relative risk is equal to 1 (23%)
- ○ F. Relative risk is not equal to 1 (7%)

Incorrect
Correct answer
C

52%
Answered correctly

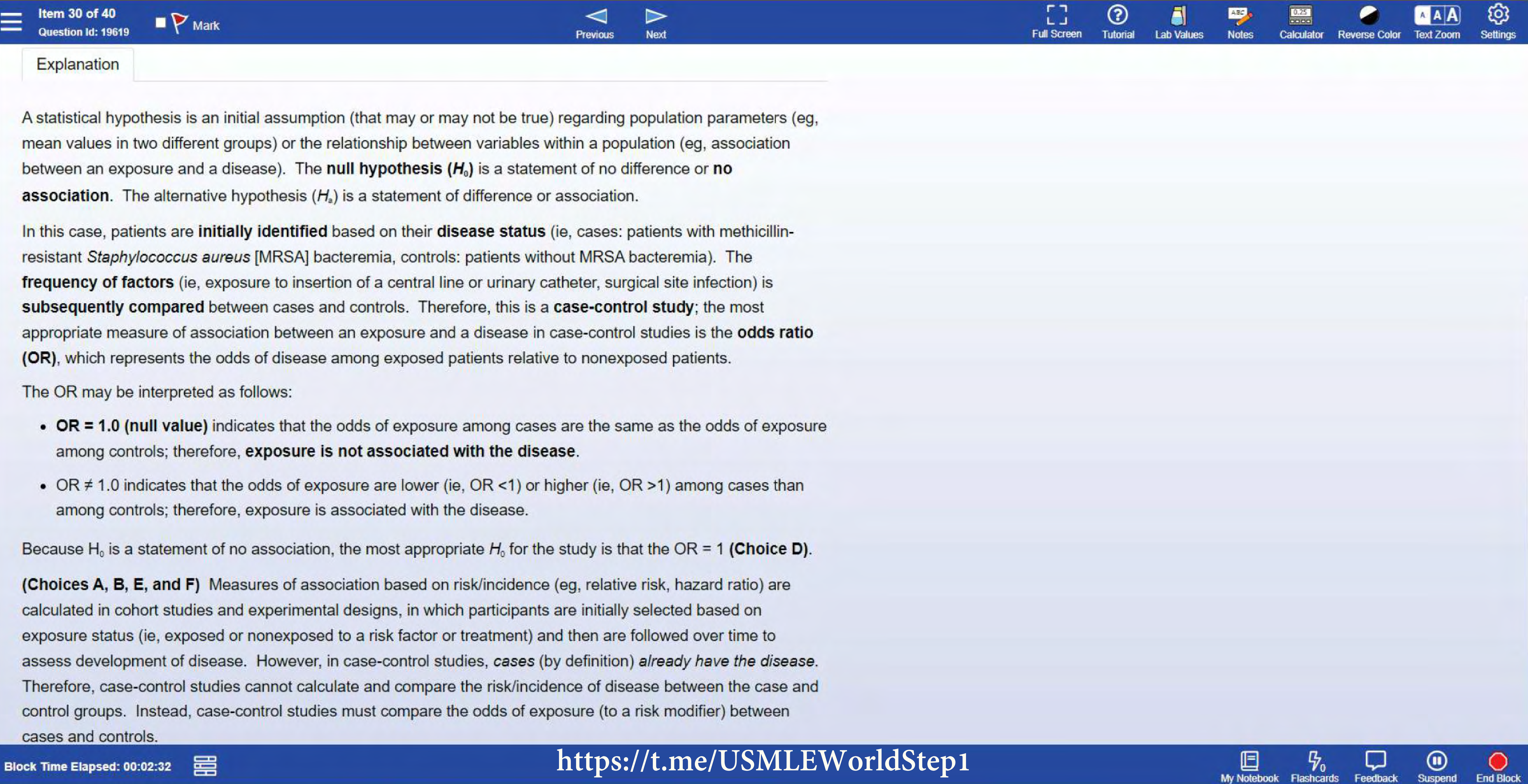
04 secs
Time Spent

2023
Version

Explanation

A statistical hypothesis is an initial assumption (that may or may not be true) regarding population parameters (eg, mean values in two different groups) or the relationship between variables within a population (eg, association between an exposure and a disease). The **null hypothesis (H_0)** is a statement of no difference or **no association**. The alternative hypothesis (H_a) is a statement of difference or association.

In this case, patients are **initially identified** based on their **disease status** (ie, cases: patients with methicillin-



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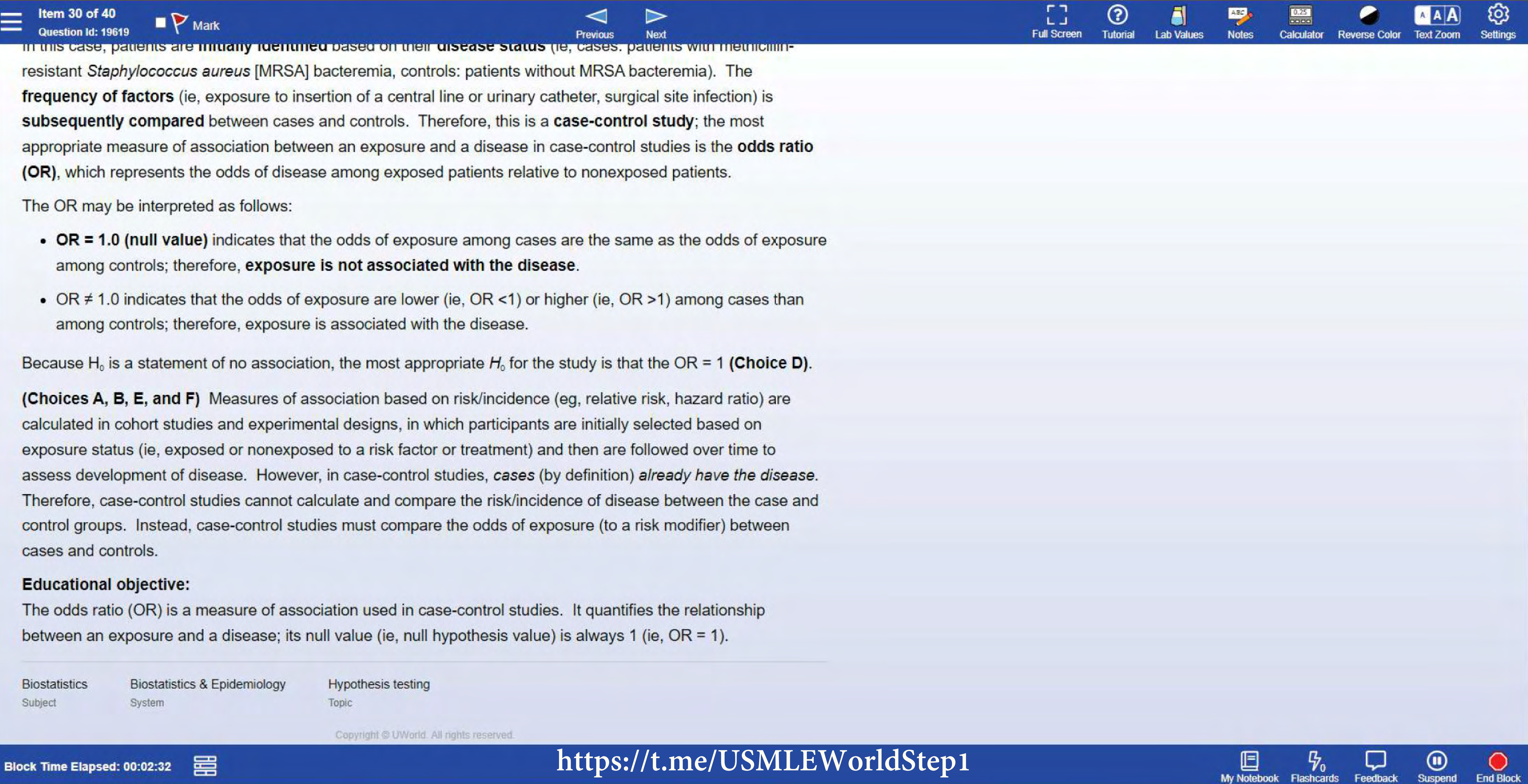
In this case, patients are **initially identified** based on their **disease status** (ie, cases: patients with methicillin-resistant *Staphylococcus aureus* [MRSA] bacteremia, controls: patients without MRSA bacteremia). The **frequency of factors** (ie, exposure to insertion of a central line or urinary catheter, surgical site infection) is **subsequently compared** between cases and controls. Therefore, this is a **case-control study**; the most appropriate measure of association between an exposure and a disease in case-control studies is the **odds ratio (OR)**, which represents the odds of disease among exposed patients relative to nonexposed patients.

The OR may be interpreted as follows:

- **OR = 1.0 (null value)** indicates that the odds of exposure among cases are the same as the odds of exposure among controls; therefore, **exposure is not associated with the disease**.
- OR ≠ 1.0 indicates that the odds of exposure are lower (ie, OR <1) or higher (ie, OR >1) among cases than among controls; therefore, exposure is associated with the disease.

Because H_0 is a statement of no association, the most appropriate H_0 for the study is that the OR = 1 **(Choice D)**.

(Choices A, B, E, and F) Measures of association based on risk/incidence (eg, relative risk, hazard ratio) are calculated in cohort studies and experimental designs, in which participants are initially selected based on exposure status (ie, exposed or nonexposed to a risk factor or treatment) and then are followed over time to assess development of disease. However, in case-control studies, *cases* (by definition) *already have the disease*. Therefore, case-control studies cannot calculate and compare the risk/incidence of disease between the case and control groups. Instead, case-control studies must compare the odds of exposure (to a risk modifier) between cases and controls.



In this case, patients are **initially identified** based on their **disease status** (ie, cases: patients with methicillin-resistant *Staphylococcus aureus* [MRSA] bacteremia, controls: patients without MRSA bacteremia). The **frequency of factors** (ie, exposure to insertion of a central line or urinary catheter, surgical site infection) is **subsequently compared** between cases and controls. Therefore, this is a **case-control study**; the most appropriate measure of association between an exposure and a disease in case-control studies is the **odds ratio (OR)**, which represents the odds of disease among exposed patients relative to nonexposed patients.

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Educational objective:

The odds ratio (OR) is a measure of association used in case-control studies. It quantifies the relationship between an exposure and a disease; its null value (ie, null hypothesis value) is always 1 (ie, OR = 1).

Biostatistics	Biostatistics & Epidemiology	Hypothesis testing
Subject	System	Topic

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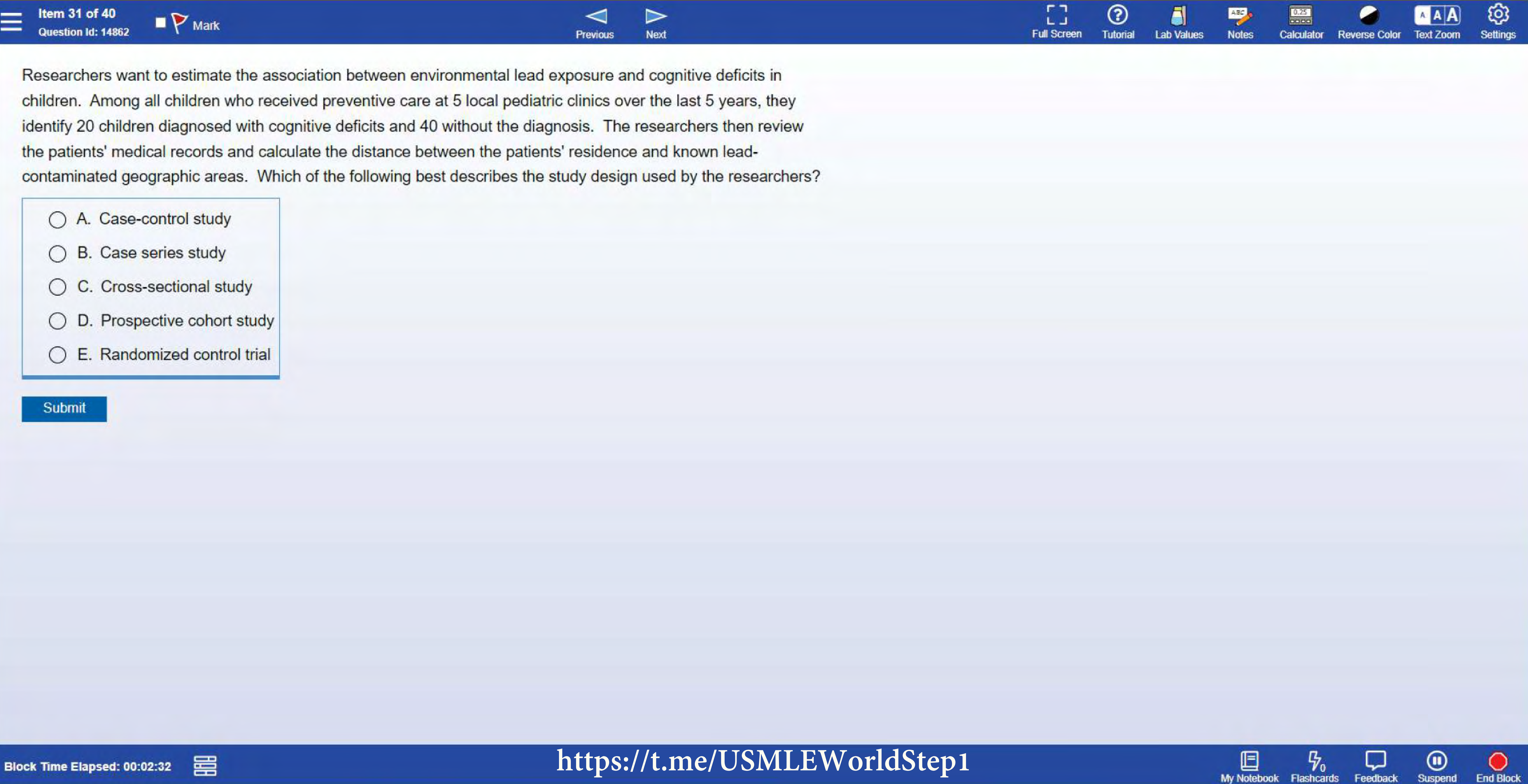
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Researchers want to estimate the association between environmental lead exposure and cognitive deficits in children. Among all children who received preventive care at 5 local pediatric clinics over the last 5 years, they identify 20 children diagnosed with cognitive deficits and 40 without the diagnosis. The researchers then review the patients' medical records and calculate the distance between the patients' residence and known lead-contaminated geographic areas. Which of the following best describes the study design used by the researchers?

- ○ A. Case-control study
- ○ B. Case series study
- ○ C. Cross-sectional study
- ○ D. Prospective cohort study
- ○ E. Randomized control trial

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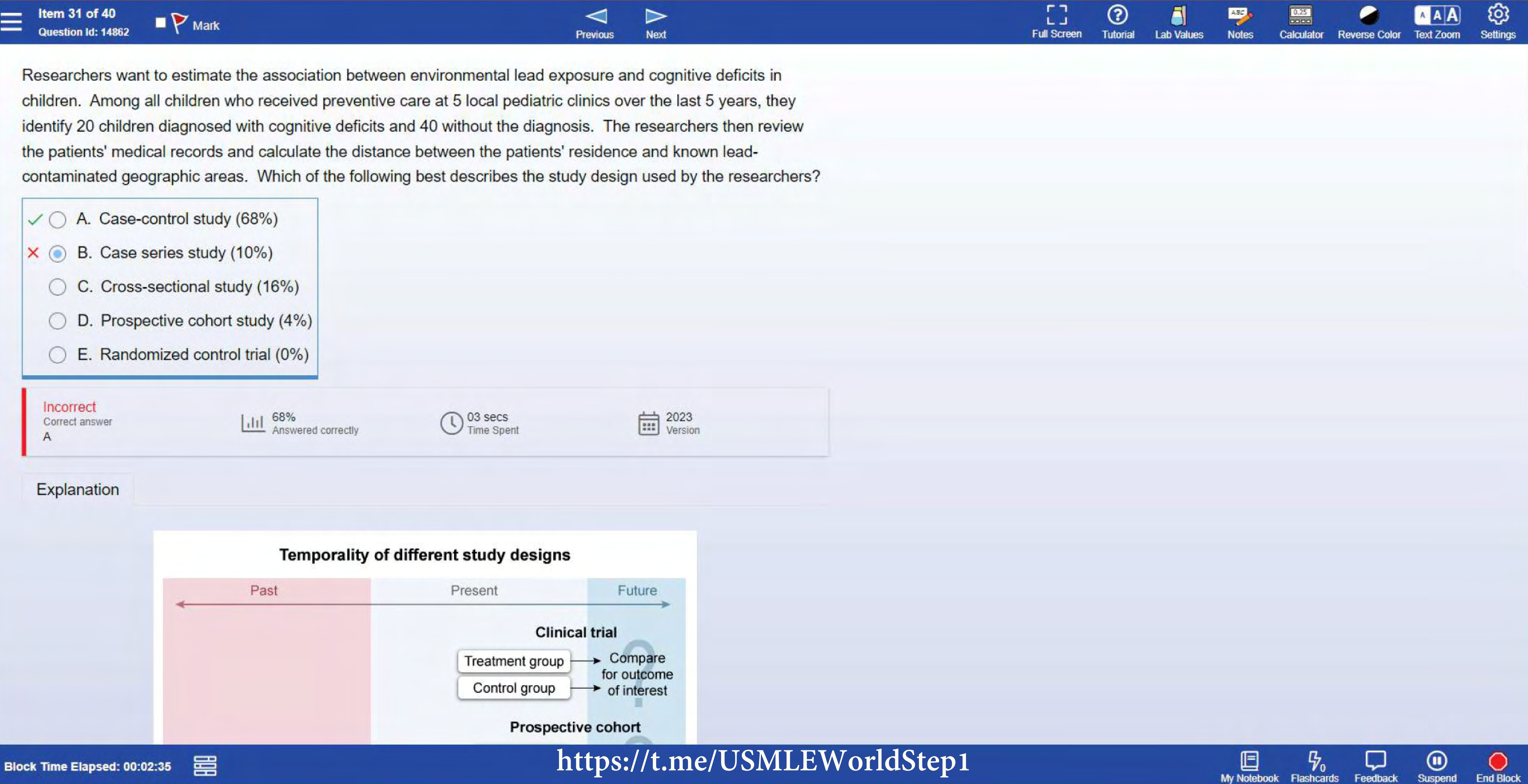
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- ✓ ○ A. Case-control study (68%)
- ✗ ● B. Case series study (10%)
- ○ C. Cross-sectional study (16%)
- ○ D. Prospective cohort study (4%)
- ○ E. Randomized control trial (0%)

Incorrect
Correct answer
A

68%
Answered correctly

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Explanation

Temporality of different study designs

Past
Present
Future
Clinical trial
Treatment group
Control group
Compare for outcome of interest
Prospective cohort

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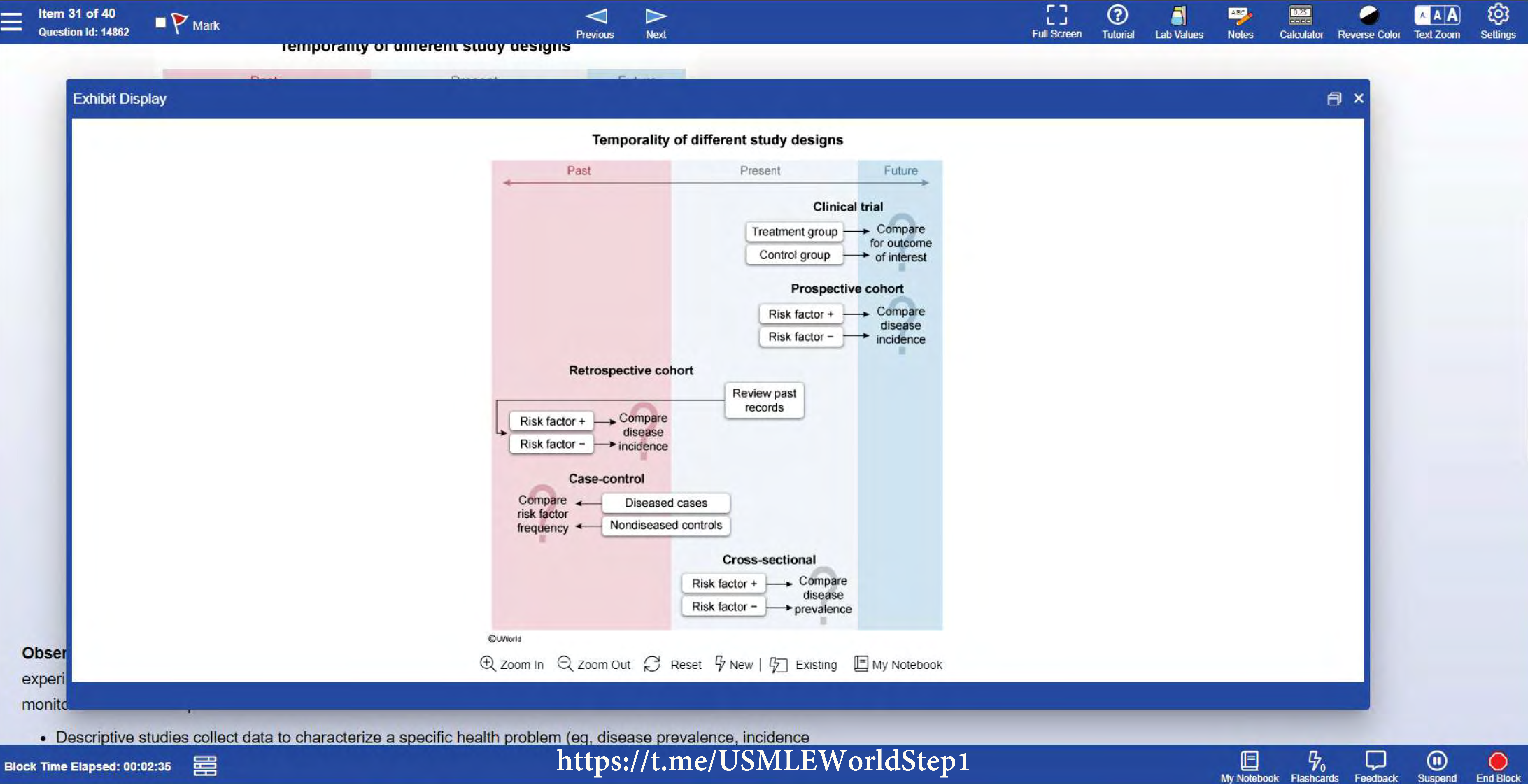
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Exhibit Display
Temporality of different study designs
Past
Present
Future
Clinical trial
Treatment group
Control group
Compare for outcome of interest
Prospective cohort
Risk factor +
Risk factor –
Compare disease incidence
Retrospective cohort
Review past records
Risk factor +
Risk factor –
Compare disease incidence
Case-control
Compare risk factor frequency
Diseased cases
Nondiseased controls
Cross-sectional
Risk factor +
Risk factor –
Compare disease prevalence
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- Descriptive studies collect data to characterize a specific health problem (eg, disease prevalence, incidence

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Observational studies (eg, case series, case-control studies, cohort studies, cross-sectional studies) differ from experimental studies (eg, clinical trials) in that the researchers passively observe the study participants rather than monitor the result of a specific intervention. Observational studies can be subdivided as follows:

- Descriptive studies collect data to characterize a specific health problem (eg, disease prevalence, incidence rates).
- Analytical studies test hypotheses to evaluate associations between risk factors and disease.

A **case-control** study is an analytical observational design in which potential participants are initially identified as "**cases**" or "**controls**" according to an **outcome status** (ie, disease of interest). In this example, children diagnosed with cognitive deficits are cases and children without cognitive deficits are controls. Once identified, cases and controls are then **assessed retrospectively** for exposure to **risk factors** of interest. In this case, the risk factor of interest is environmental lead exposure, as measured by the distance between the patients' residence and known lead-contaminated areas. Finally, the prevalence of exposure to the risk factors (ie, frequency of exposure) is compared between cases and controls to estimate the **association** between the risk factors and the outcomes.

(Choice B) A case series study is a descriptive study that tracks patients with a known condition (eg, exposure, risk factor, disease) to document the natural history or response to treatment. Unlike a case-control study, a case series is purely descriptive and cannot establish associations.

(Choice C) Cross-sectional studies may evaluate associations between risk factors and outcomes of interest. However, unlike in case-control studies (participants selected based on the outcome status), the participants in a cross-sectional study are selected based on the inclusion and exclusion criteria set for the study.

(Choice D) In cohort studies, 2 groups of individuals (ie, cohorts) are initially identified based on their exposure status to a specific risk factor (eg, environmental lead exposure) rather than based on their outcome status (eg, cognitive deficits), as seen in this example. The cohorts are then followed over time for development of the outcome.

(Choice E) A randomized clinical trial would follow individuals who have been randomized to either a treatment

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(Choice E) A randomized clinical trial would follow individuals who have been randomized to either a treatment arm or a control arm and compare the effect of the intervention.

Educational objective:

A case-control study is an observational study design; it begins with selecting individuals who have the outcome ("cases") and individuals who do not have the outcome ("controls") and then retrospectively comparing their history of exposure to risk factors.

Biostatistics	Biostatistics & Epidemiology	Study designs
Subject	System	Topic

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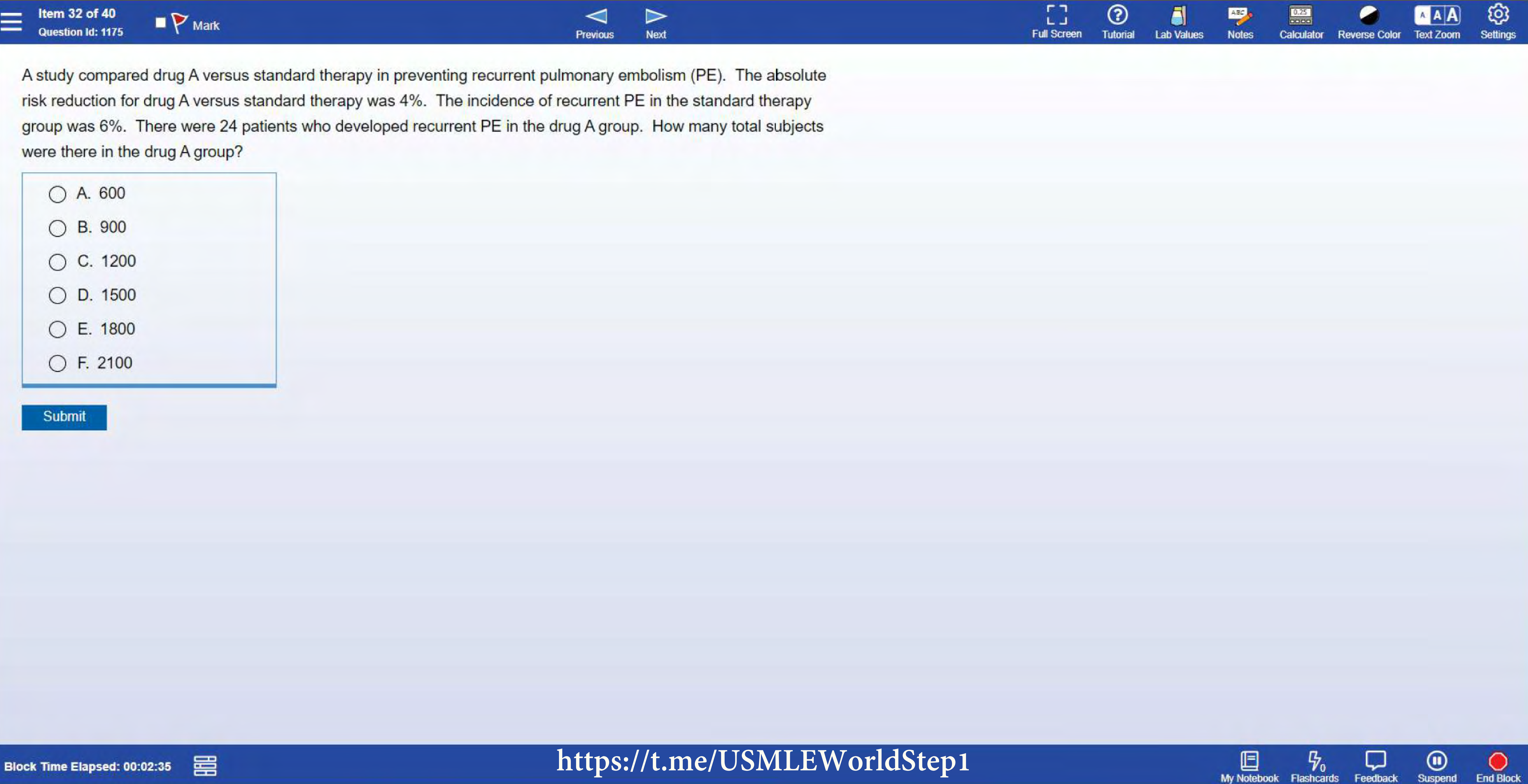
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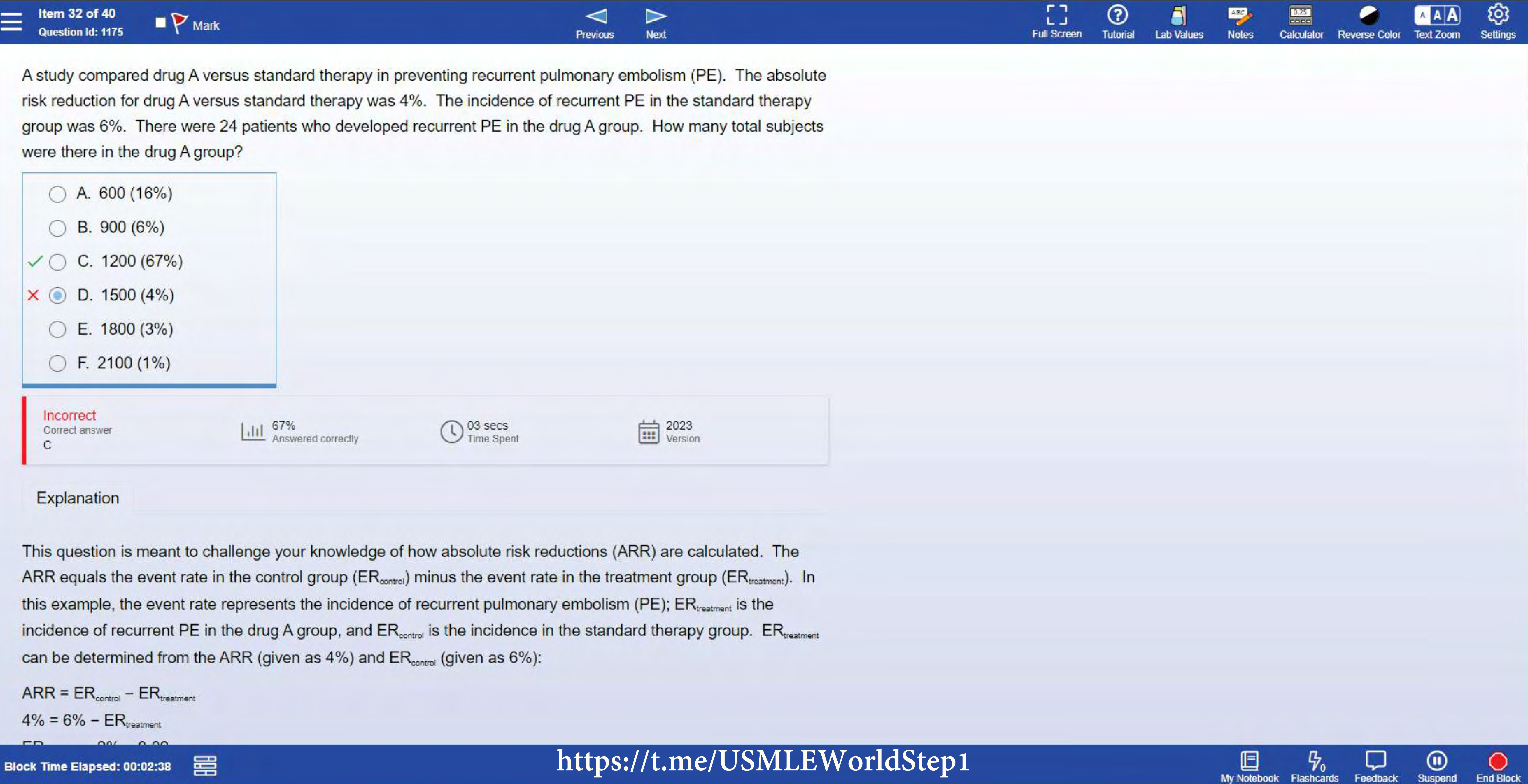
A study compared drug A versus standard therapy in preventing recurrent pulmonary embolism (PE). The absolute risk reduction for drug A versus standard therapy was 4%. The incidence of recurrent PE in the standard therapy group was 6%. There were 24 patients who developed recurrent PE in the drug A group. How many total subjects were there in the drug A group?

- ○ A. 600
- ○ B. 900
- ○ C. 1200
- ○ D. 1500
- ○ E. 1800
- ○ F. 2100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- ○ A. 600 (16%)
- ○ B. 900 (6%)
- ✓ ○ C. 1200 (67%)
- ✗ ● D. 1500 (4%)
- ○ E. 1800 (3%)
- ○ F. 2100 (1%)

Incorrect
Correct answer
C

67%
Answered correctly

03 secs
Time Spent

2023
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Explanation

This question is meant to challenge your knowledge of how absolute risk reductions (ARR) are calculated. The ARR equals the event rate in the control group ($ER_{control}$) minus the event rate in the treatment group ($ER_{treatment}$). In this example, the event rate represents the incidence of recurrent pulmonary embolism (PE); $ER_{treatment}$ is the incidence of recurrent PE in the drug A group, and $ER_{control}$ is the incidence in the standard therapy group. $ER_{treatment}$ can be determined from the ARR (given as 4%) and $ER_{control}$ (given as 6%):

$ARR = ER_{control} - ER_{treatment}$

$4\% = 6\% - ER_{treatment}$

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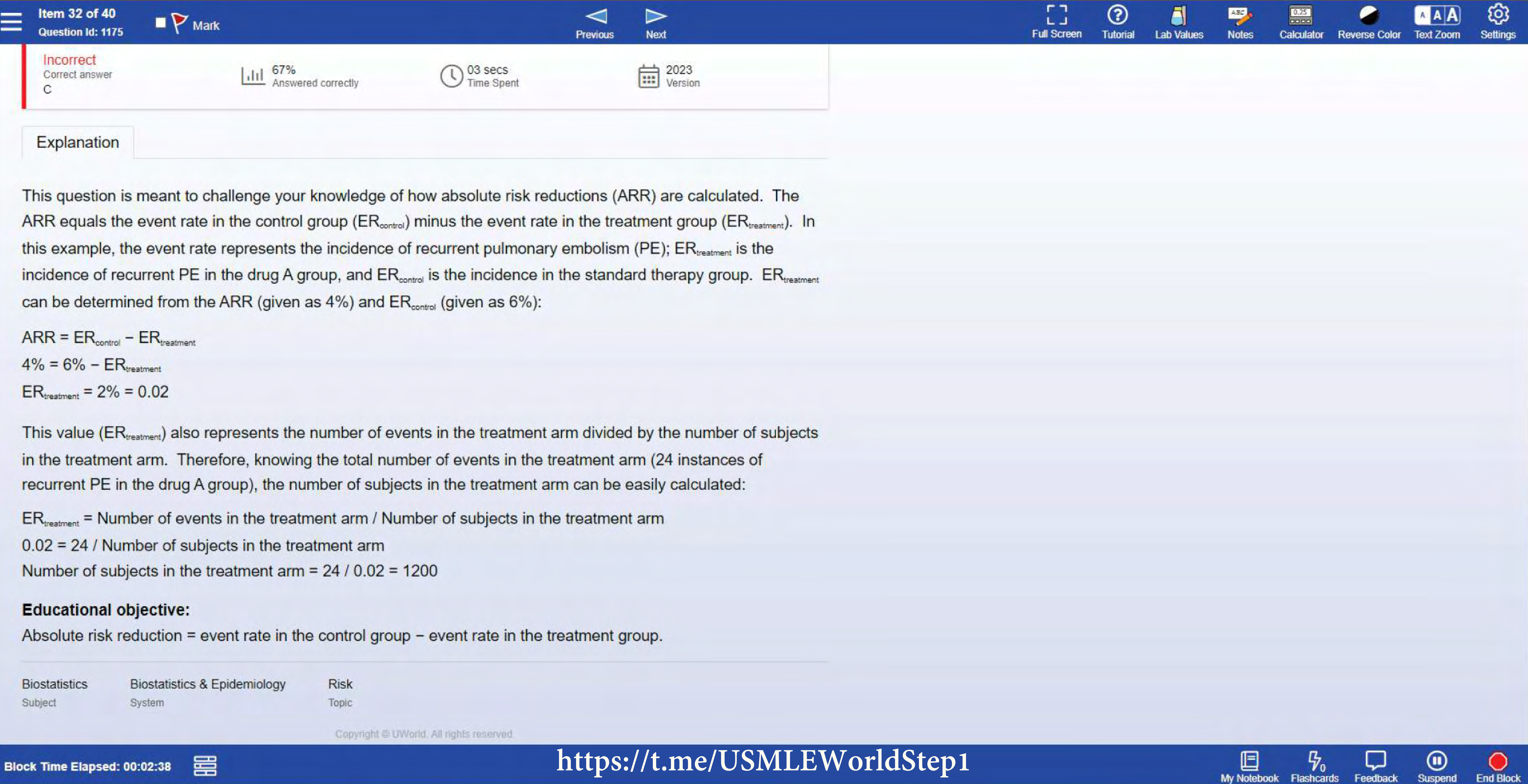
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Incorrect
Correct answer
C

67%
Answered correctly

03 secs
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Explanation

This question is meant to challenge your knowledge of how absolute risk reductions (ARR) are calculated. The ARR equals the event rate in the control group (ER_{control}) minus the event rate in the treatment group ($ER_{\text{treatment}}$). In this example, the event rate represents the incidence of recurrent pulmonary embolism (PE); $ER_{\text{treatment}}$ is the incidence of recurrent PE in the drug A group, and ER_{control} is the incidence in the standard therapy group. $ER_{\text{treatment}}$ can be determined from the ARR (given as 4%) and ER_{control} (given as 6%):

$ARR = ER_{\text{control}} - ER_{\text{treatment}}$
$4\% = 6\% - ER_{\text{treatment}}$
$ER_{\text{treatment}} = 2\% = 0.02$

This value ($ER_{\text{treatment}}$) also represents the number of events in the treatment arm divided by the number of subjects in the treatment arm. Therefore, knowing the total number of events in the treatment arm (24 instances of recurrent PE in the drug A group), the number of subjects in the treatment arm can be easily calculated:

$ER_{\text{treatment}}$ = Number of events in the treatment arm / Number of subjects in the treatment arm
0.02 = 24 / Number of subjects in the treatment arm
Number of subjects in the treatment arm = 24 / 0.02 = 1200

Educational objective:
Absolute risk reduction = event rate in the control group − event rate in the treatment group.

Biostatistics	Biostatistics & Epidemiology	Risk
Subject	System	Topic

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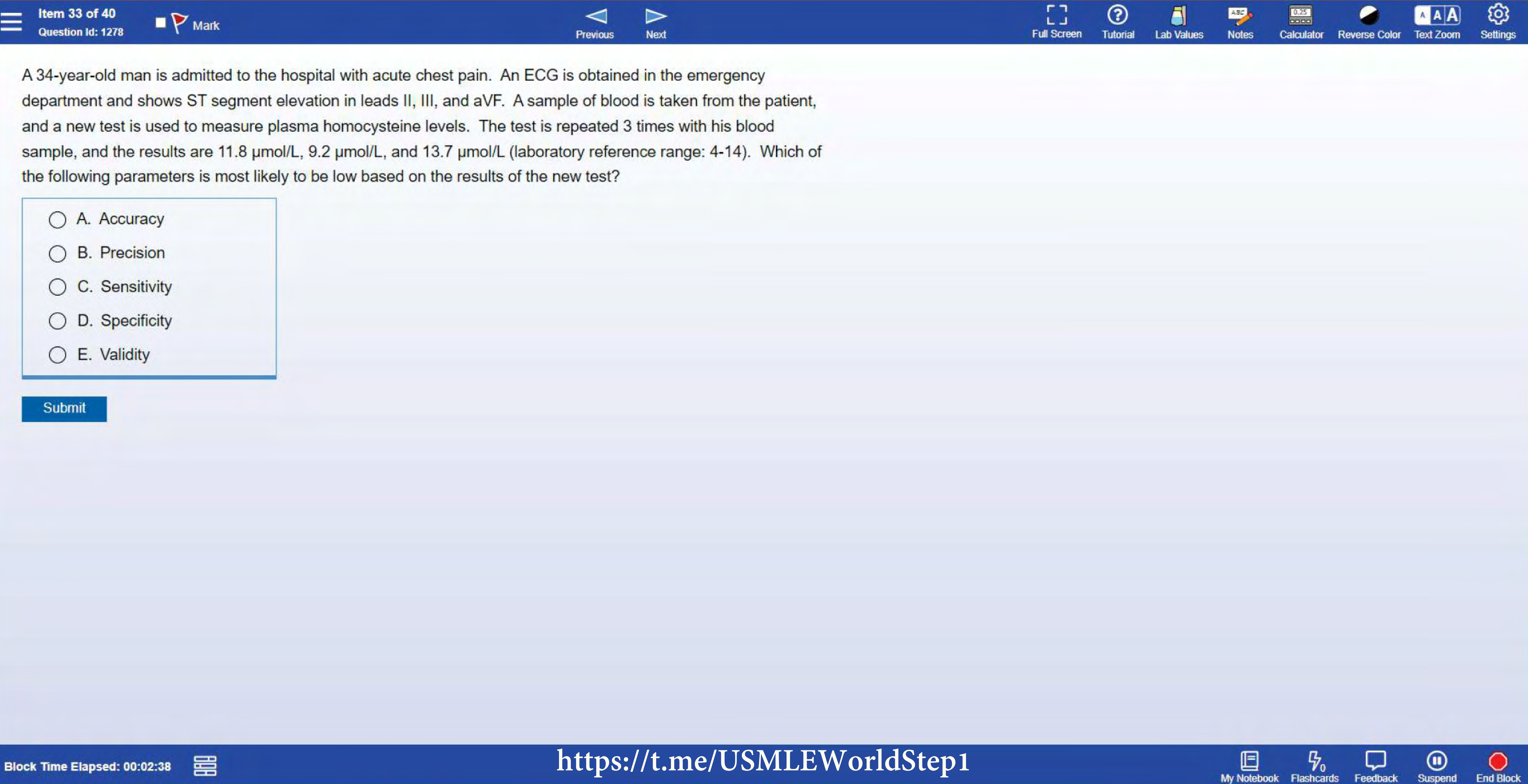
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A 34-year-old man is admitted to the hospital with acute chest pain. An ECG is obtained in the emergency department and shows ST segment elevation in leads II, III, and aVF. A sample of blood is taken from the patient, and a new test is used to measure plasma homocysteine levels. The test is repeated 3 times with his blood sample, and the results are 11.8 µmol/L, 9.2 µmol/L, and 13.7 µmol/L (laboratory reference range: 4-14). Which of the following parameters is most likely to be low based on the results of the new test?

○ A. Accuracy

○ B. Precision

○ C. Sensitivity

○ D. Specificity

○ E. Validity

A 34-year-old man is admitted to the hospital with acute chest pain. An ECG is obtained in the emergency department and shows ST segment elevation in leads II, III, and aVF. A sample of blood is taken from the patient, and a new test is used to measure plasma homocysteine levels. The test is repeated 3 times with his blood sample, and the results are 11.8 µmol/L, 9.2 µmol/L, and 13.7 µmol/L (laboratory reference range: 4-14). Which of the following parameters is most likely to be low based on the results of the new test?

○ A. Accuracy (12%)
✓ ● B. Precision (79%)
○ C. Sensitivity (2%)
○ D. Specificity (2%)
○ E. Validity (3%)

Correct
79% Answered correctly
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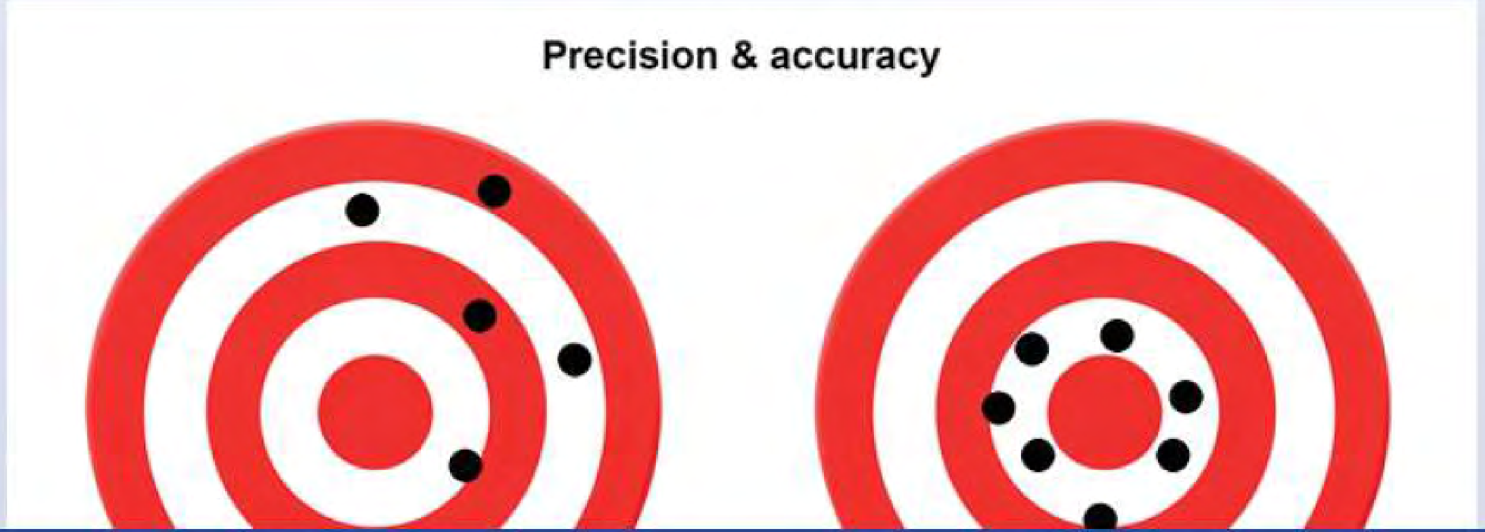
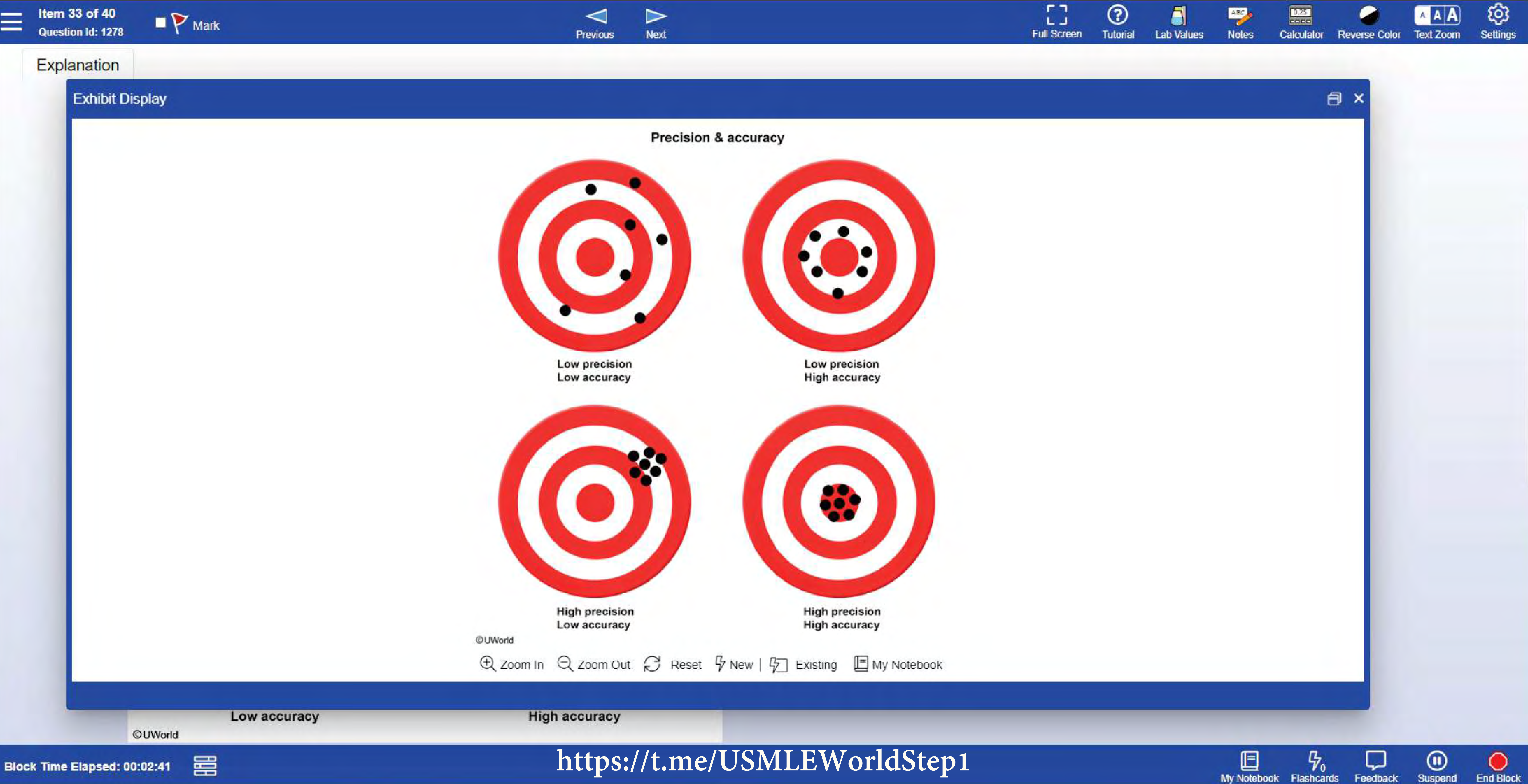
Explanation



Precision & accuracy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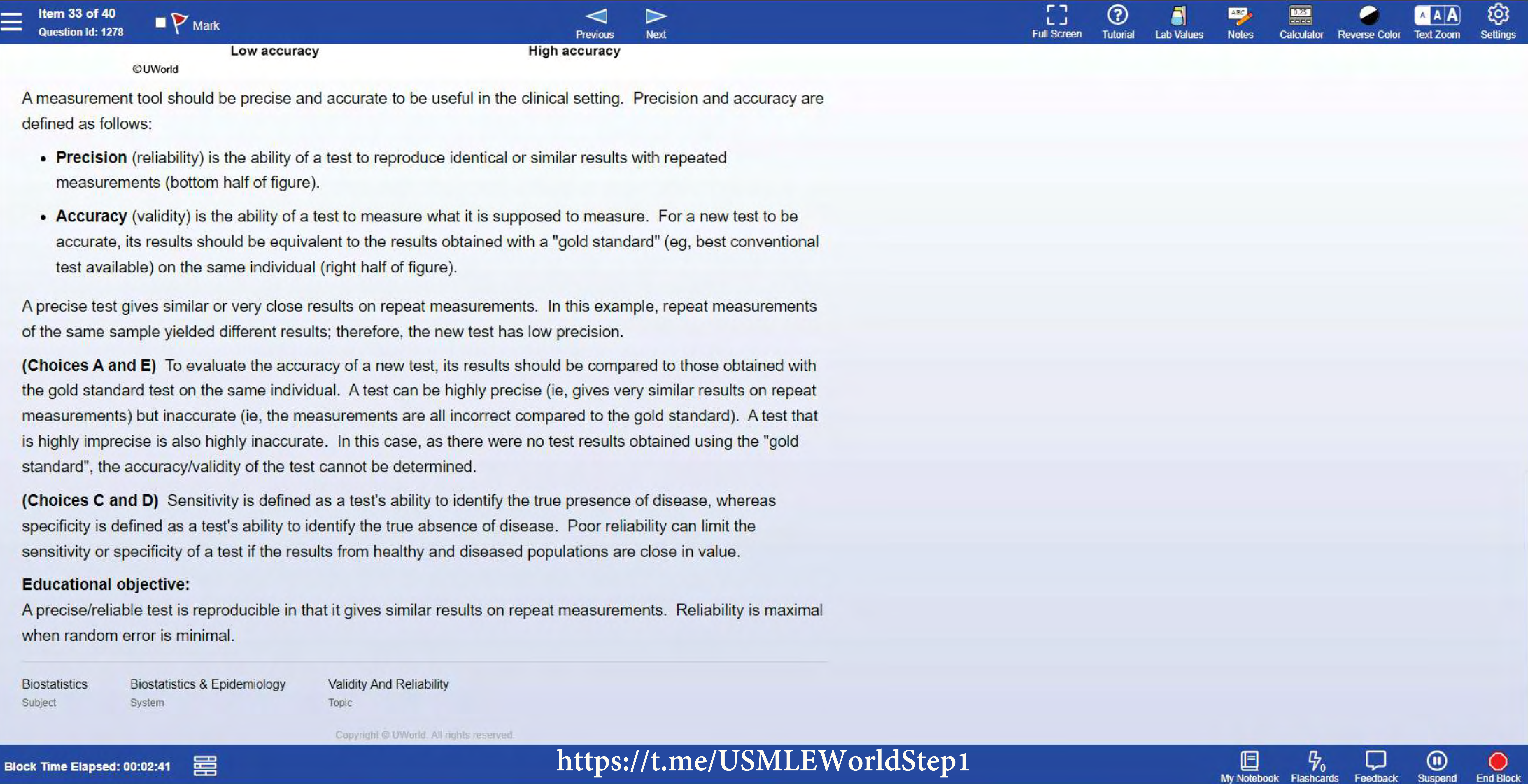
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A measurement tool should be precise and accurate to be useful in the clinical setting. Precision and accuracy are defined as follows:

- **Precision** (reliability) is the ability of a test to reproduce identical or similar results with repeated measurements (bottom half of figure).
- **Accuracy** (validity) is the ability of a test to measure what it is supposed to measure. For a new test to be accurate, its results should be equivalent to the results obtained with a "gold standard" (eg, best conventional test available) on the same individual (right half of figure).

A precise test gives similar or very close results on repeat measurements. In this example, repeat measurements of the same sample yielded different results; therefore, the new test has low precision.

(Choices A and E) To evaluate the accuracy of a new test, its results should be compared to those obtained with the gold standard test on the same individual. A test can be highly precise (ie, gives very similar results on repeat measurements) but inaccurate (ie, the measurements are all incorrect compared to the gold standard). A test that is highly imprecise is also highly inaccurate. In this case, as there were no test results obtained using the "gold standard", the accuracy/validity of the test cannot be determined.

(Choices C and D) Sensitivity is defined as a test's ability to identify the true presence of disease, whereas specificity is defined as a test's ability to identify the true absence of disease. Poor reliability can limit the sensitivity or specificity of a test if the results from healthy and diseased populations are close in value.

Educational objective:

A precise/reliable test is reproducible in that it gives similar results on repeat measurements. Reliability is maximal when random error is minimal.

Biostatistics	Biostatistics & Epidemiology	Validity And Reliability
Subject	System	Topic

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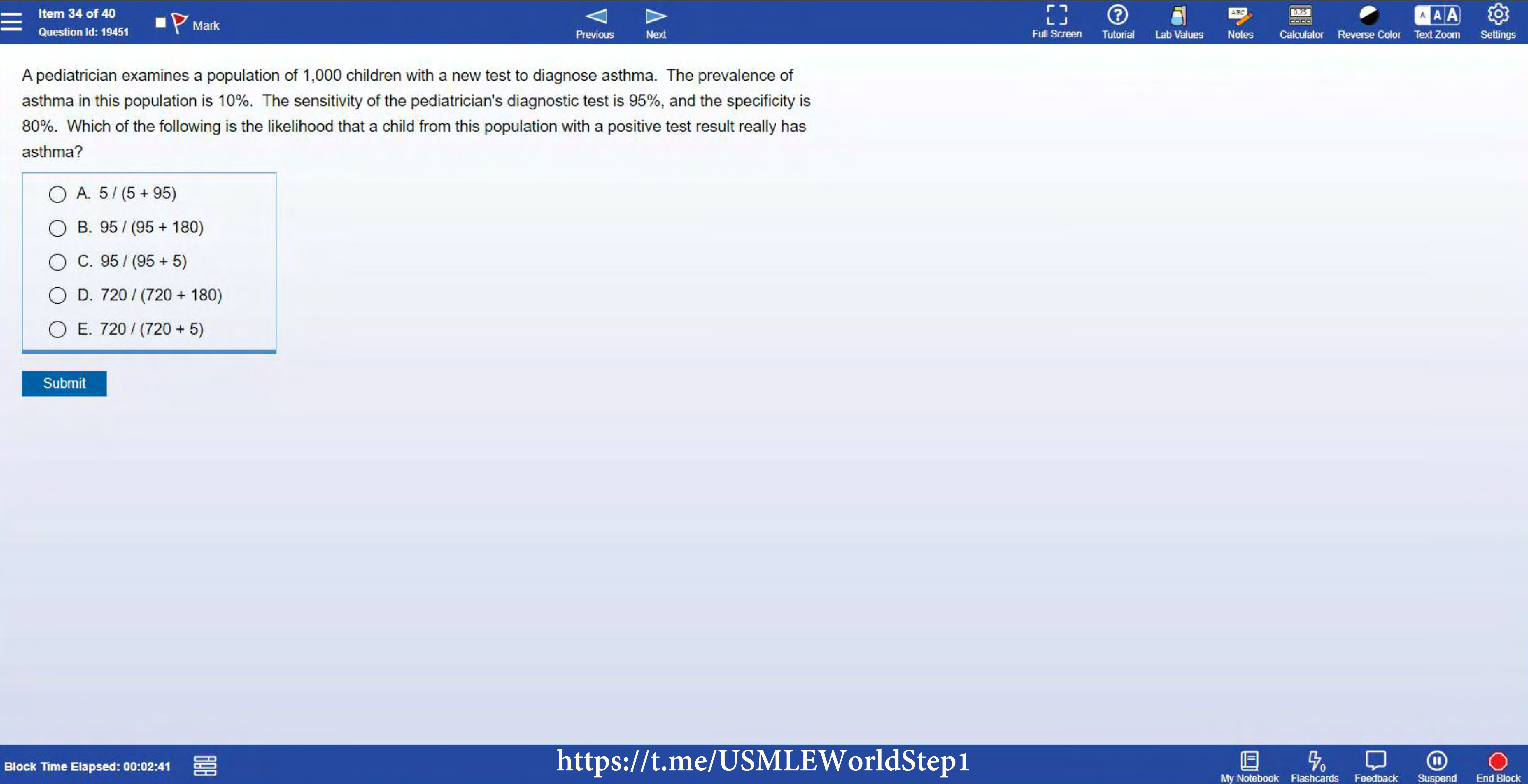
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A pediatrician examines a population of 1,000 children with a new test to diagnose asthma. The prevalence of asthma in this population is 10%. The sensitivity of the pediatrician's diagnostic test is 95%, and the specificity is 80%. Which of the following is the likelihood that a child from this population with a positive test result really has asthma?

○ A. 5 / (5 + 95)
○ B. 95 / (95 + 180)
○ C. 95 / (95 + 5)
○ D. 720 / (720 + 180)
○ E. 720 / (720 + 5)

A pediatrician examines a population of 1,000 children with a new test to diagnose asthma. The prevalence of asthma in this population is 10%. The sensitivity of the pediatrician's diagnostic test is 95%, and the specificity is 80%. Which of the following is the likelihood that a child from this population with a positive test result really has asthma?

○ A. 5 / (5 + 95) (2%)

✓ ● B. 95 / (95 + 180) (62%)

○ C. 95 / (95 + 5) (23%)

○ D. 720 / (720 + 180) (9%)

○ E. 720 / (720 + 5) (1%)

Correct

62% Answered correctly

03 secs Time Spent

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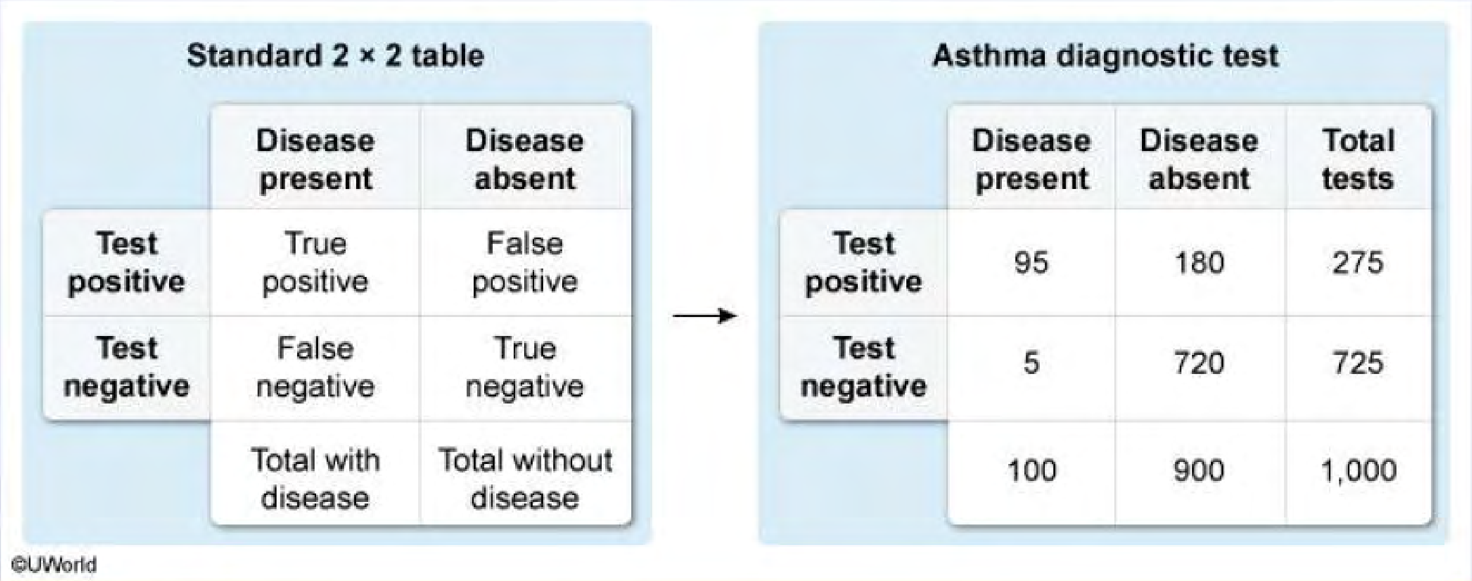
Explanation



Standard 2 × 2 table

	Disease present	Disease absent
Test positive	True positive	False positive
Test negative	False negative	True negative
	Total with disease	Total without disease

→

Asthma diagnostic test

	Disease present	Disease absent	Total tests
Test positive	95	180	275
Test negative	5	720	725
	100	900	1,000

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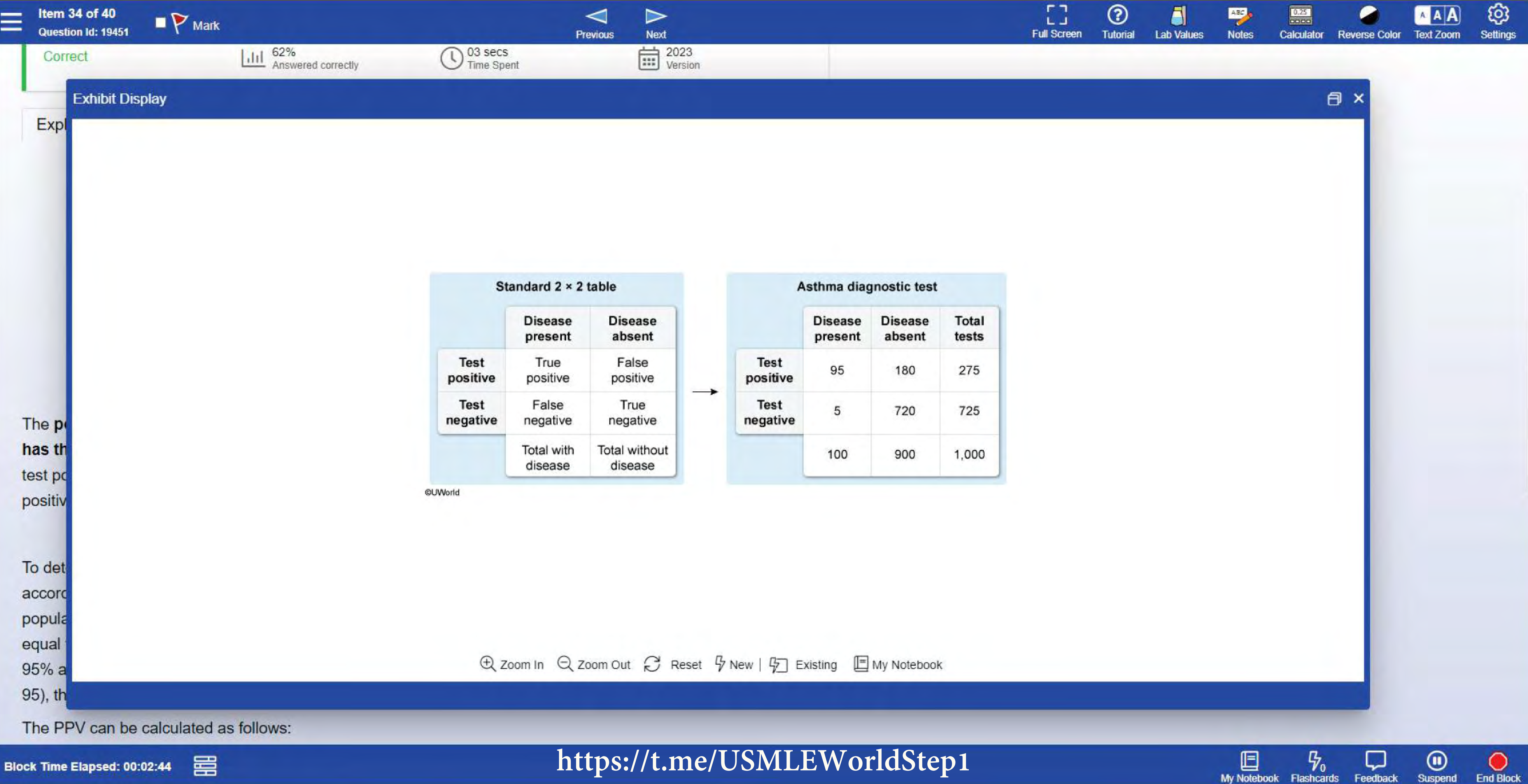
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Standard 2 × 2 table

	Disease present	Disease absent
Test positive	True positive	False positive
Test negative	False negative	True negative
	Total with disease	Total without disease

→

Asthma diagnostic test

	Disease present	Disease absent	Total tests
Test positive	95	180	275
Test negative	5	720	725
	100	900	1,000

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The PPV can be calculated as follows:

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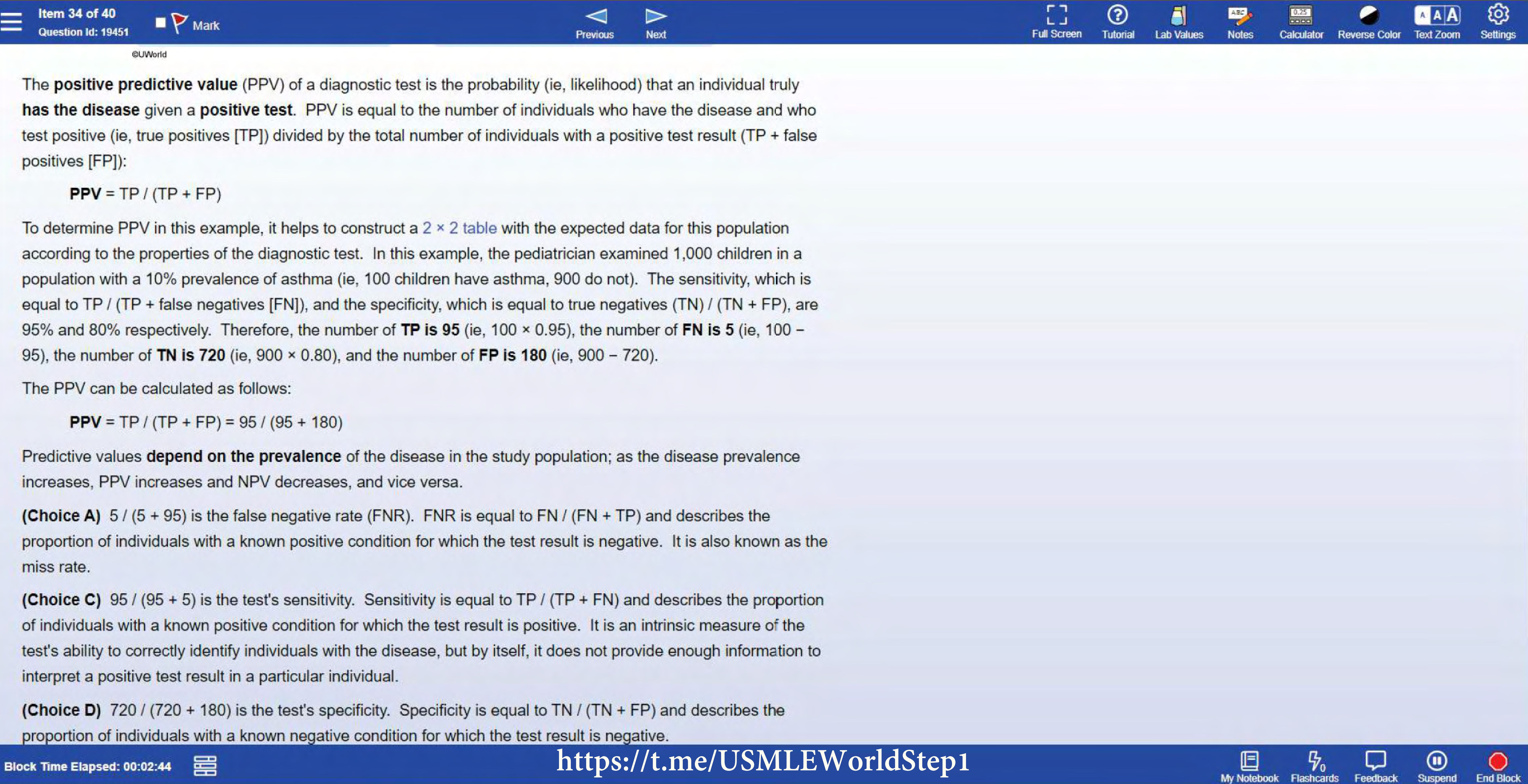
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The **positive predictive value** (PPV) of a diagnostic test is the probability (ie, likelihood) that an individual truly **has the disease** given a **positive test**. PPV is equal to the number of individuals who have the disease and who test positive (ie, true positives [TP]) divided by the total number of individuals with a positive test result (TP + false positives [FP]):

PPV = TP / (TP + FP)

To determine PPV in this example, it helps to construct a 2 × 2 table with the expected data for this population according to the properties of the diagnostic test. In this example, the pediatrician examined 1,000 children in a population with a 10% prevalence of asthma (ie, 100 children have asthma, 900 do not). The sensitivity, which is equal to TP / (TP + false negatives [FN]), and the specificity, which is equal to true negatives (TN) / (TN + FP), are 95% and 80% respectively. Therefore, the number of **TP is 95** (ie, 100 × 0.95), the number of **FN is 5** (ie, 100 – 95), the number of **TN is 720** (ie, 900 × 0.80), and the number of **FP is 180** (ie, 900 – 720).

The PPV can be calculated as follows:

PPV = TP / (TP + FP) = 95 / (95 + 180)

Predictive values **depend on the prevalence** of the disease in the study population; as the disease prevalence increases, PPV increases and NPV decreases, and vice versa.

(Choice A) 5 / (5 + 95) is the false negative rate (FNR). FNR is equal to FN / (FN + TP) and describes the proportion of individuals with a known positive condition for which the test result is negative. It is also known as the miss rate.

(Choice C) 95 / (95 + 5) is the test's sensitivity. Sensitivity is equal to TP / (TP + FN) and describes the proportion of individuals with a known positive condition for which the test result is positive. It is an intrinsic measure of the test's ability to correctly identify individuals with the disease, but by itself, it does not provide enough information to interpret a positive test result in a particular individual.

(Choice D) 720 / (720 + 180) is the test's specificity. Specificity is equal to TN / (TN + FP) and describes the proportion of individuals with a known negative condition for which the test result is negative.

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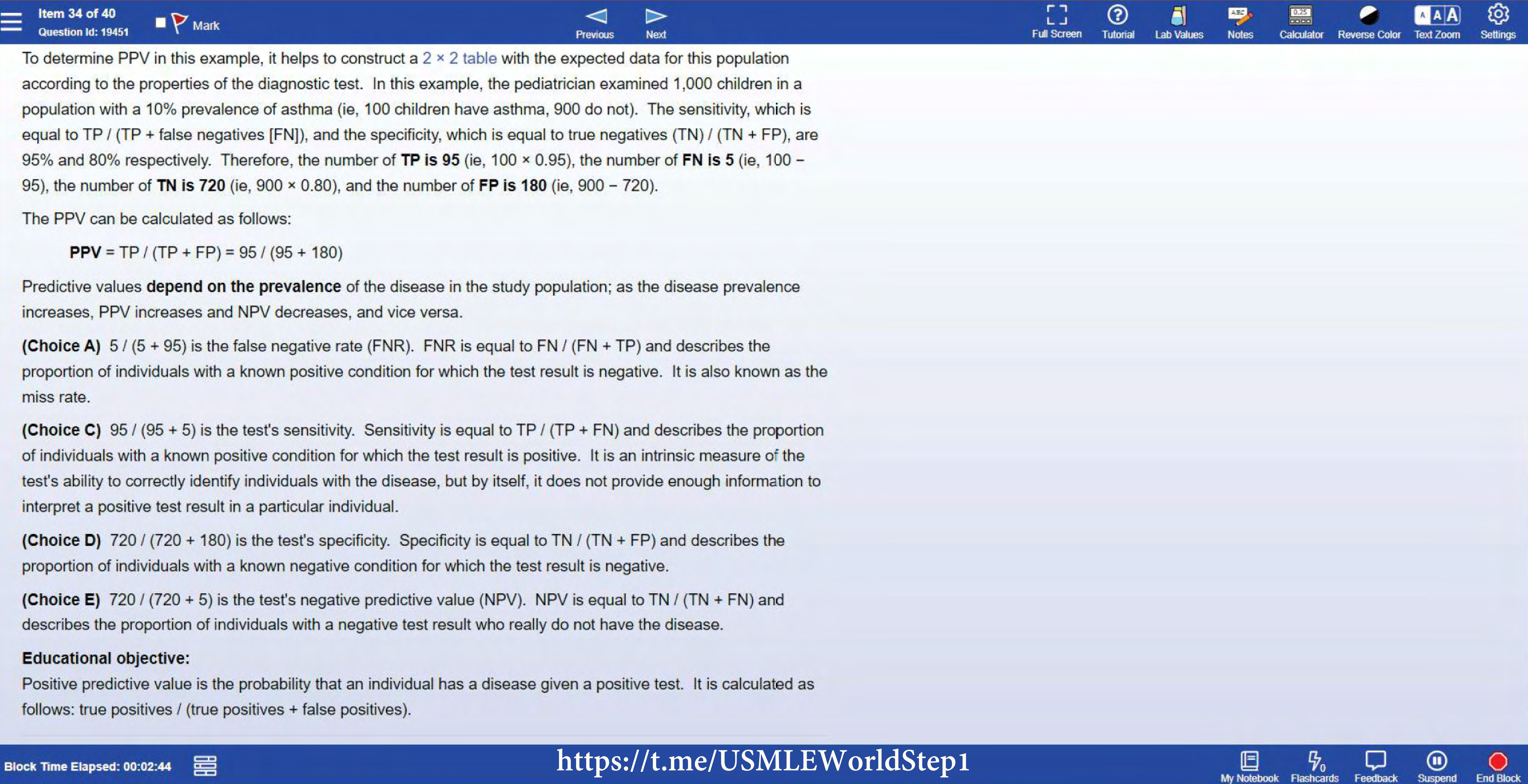


To determine PPV in this example, it helps to construct a 2 × 2 table with the expected data for this population according to the properties of the diagnostic test. In this example, the pediatrician examined 1,000 children in a population with a 10% prevalence of asthma (ie, 100 children have asthma, 900 do not). The sensitivity, which is equal to TP / (TP + false negatives [FN]), and the specificity, which is equal to true negatives (TN) / (TN + FP), are 95% and 80% respectively. Therefore, the number of **TP is 95** (ie, 100 × 0.95), the number of **FN is 5** (ie, 100 – 95), the number of **TN is 720** (ie, 900 × 0.80), and the number of **FP is 180** (ie, 900 – 720).

The PPV can be calculated as follows:

PPV = TP / (TP + FP) = 95 / (95 + 180)

Predictive values **depend on the prevalence** of the disease in the study population; as the disease prevalence increases, PPV increases and NPV decreases, and vice versa.

(Choice A) 5 / (5 + 95) is the false negative rate (FNR). FNR is equal to FN / (FN + TP) and describes the proportion of individuals with a known positive condition for which the test result is negative. It is also known as the miss rate.

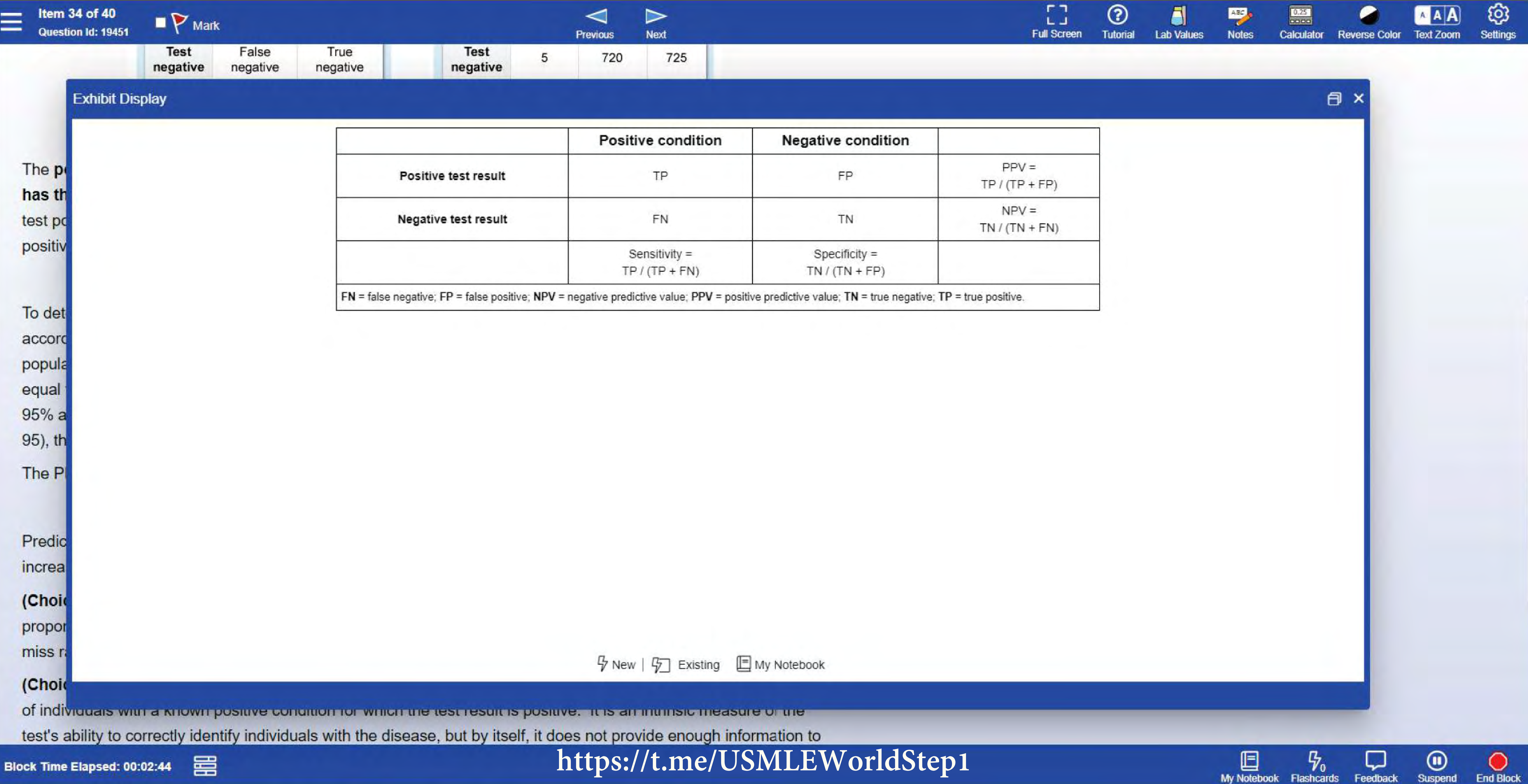
(Choice C) 95 / (95 + 5) is the test's sensitivity. Sensitivity is equal to TP / (TP + FN) and describes the proportion of individuals with a known positive condition for which the test result is positive. It is an intrinsic measure of the test's ability to correctly identify individuals with the disease, but by itself, it does not provide enough information to interpret a positive test result in a particular individual.

(Choice D) 720 / (720 + 180) is the test's specificity. Specificity is equal to TN / (TN + FP) and describes the proportion of individuals with a known negative condition for which the test result is negative.

(Choice E) 720 / (720 + 5) is the test's negative predictive value (NPV). NPV is equal to TN / (TN + FN) and describes the proportion of individuals with a negative test result who really do not have the disease.

Educational objective:

Positive predictive value is the probability that an individual has a disease given a positive test. It is calculated as follows: true positives / (true positives + false positives).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Test negative	False negative	True negative

Test negative	5	720	725

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	Positive condition	Negative condition	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

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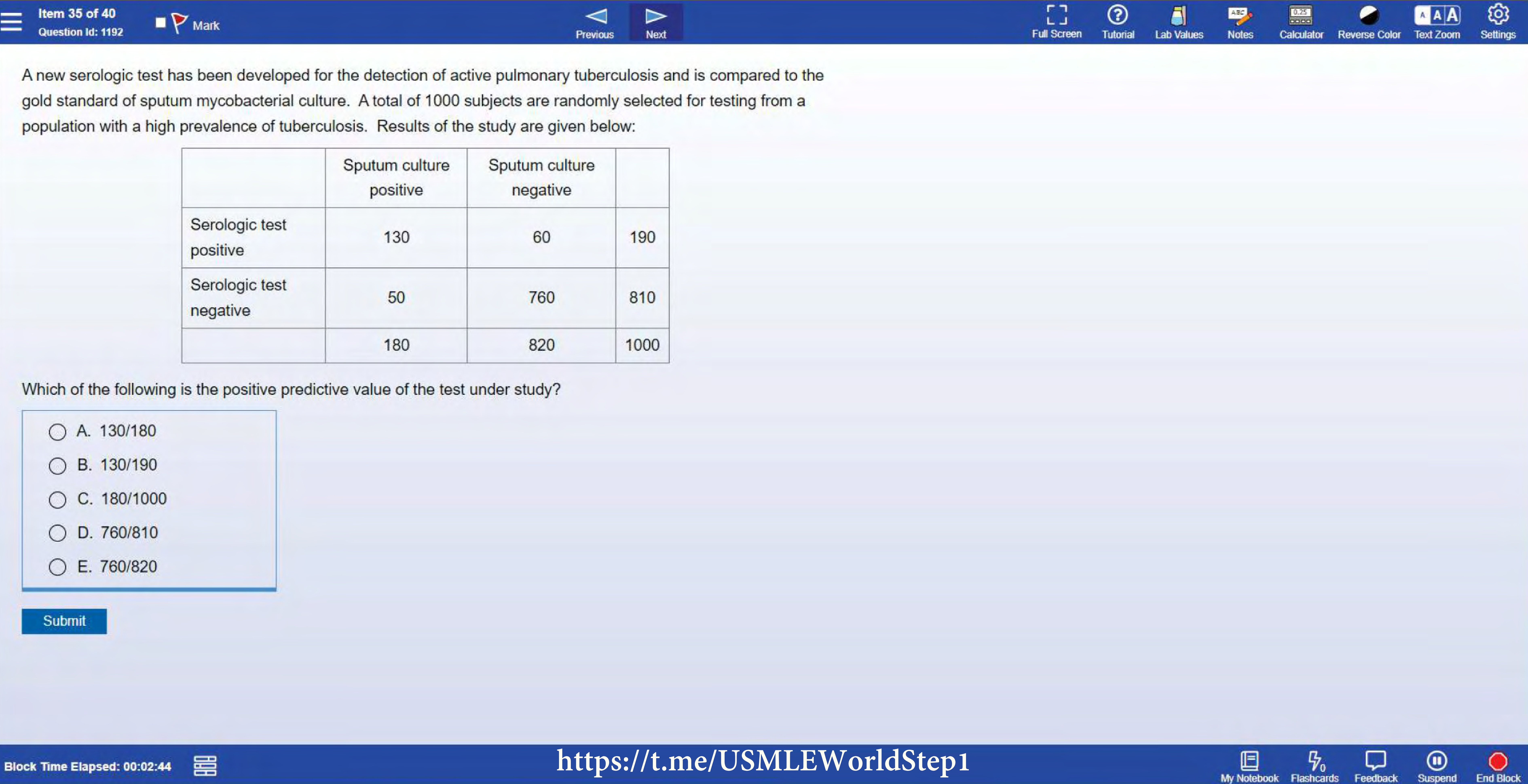
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A new serologic test has been developed for the detection of active pulmonary tuberculosis and is compared to the gold standard of sputum mycobacterial culture. A total of 1000 subjects are randomly selected for testing from a population with a high prevalence of tuberculosis. Results of the study are given below:

	Sputum culture positive	Sputum culture negative	
Serologic test positive	130	60	190
Serologic test negative	50	760	810
	180	820	1000

Which of the following is the positive predictive value of the test under study?

○ A. 130/180
○ B. 130/190
○ C. 180/1000
○ D. 760/810
○ E. 760/820

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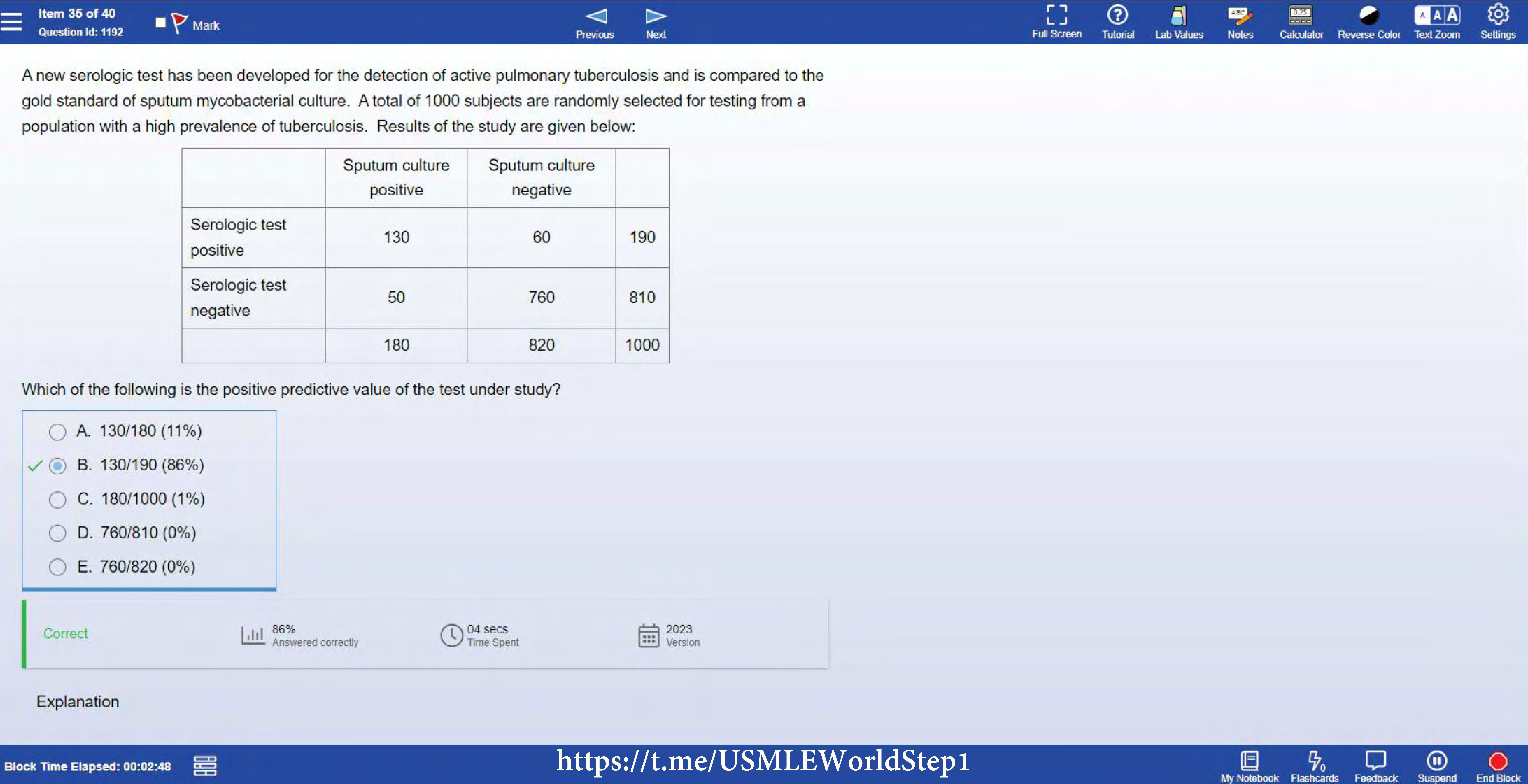
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A new serologic test has been developed for the detection of active pulmonary tuberculosis and is compared to the gold standard of sputum mycobacterial culture. A total of 1000 subjects are randomly selected for testing from a population with a high prevalence of tuberculosis. Results of the study are given below:

	Sputum culture positive	Sputum culture negative	
Serologic test positive	130	60	190
Serologic test negative	50	760	810
	180	820	1000

Which of the following is the positive predictive value of the test under study?

○ A. 130/180 (11%)

✓ ● B. 130/190 (86%)

○ C. 180/1000 (1%)

○ D. 760/810 (0%)

○ E. 760/820 (0%)

Correct

86% Answered correctly

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Explanation

The **positive predictive value (PPV)** of a test answers the question: If the test result is positive, what is the probability that a patient has the disease? PPV is calculated as the proportion of subjects who truly have the disease among all those with a positive test result. In contrast, the **negative predictive value (NPV)** of a test answers the question: If the test result is negative, what is the probability that a patient does not have the disease? It is calculated as the proportion of subjects who are truly free of disease among all those with a negative test result. Predictive values are of prime importance to physicians because, in clinical practice, patients will present more often with a positive or negative test than with a defined diseased or disease-free state.

Consider the following 2 × 2 (contingency) table:

	Positive condition	**Negative condition**	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

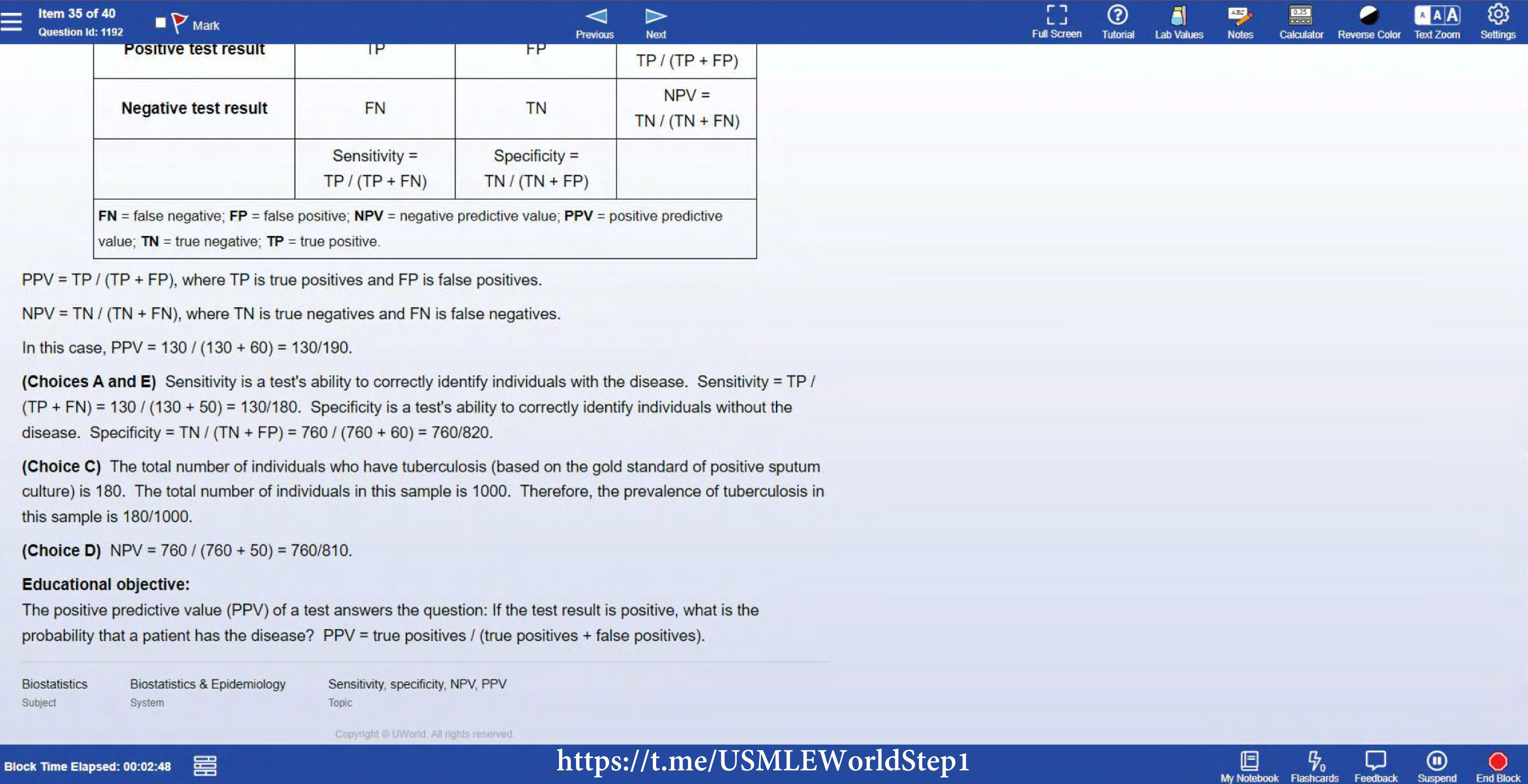
FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

PPV = TP / (TP + FP), where TP is true positives and FP is false positives.

NPV = TN / (TN + FN), where TN is true negatives and FN is false negatives.

In this case, PPV = 130 / (130 + 60) = 130/190.

(Choices A and E) Sensitivity is a test's ability to correctly identify individuals with the disease. Sensitivity = TP / (TP + FN) = 130 / (130 + 50) = 130/180. Specificity is a test's ability to correctly identify individuals without the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Positive test result	TP	FP	TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

PPV = TP / (TP + FP), where TP is true positives and FP is false positives.

NPV = TN / (TN + FN), where TN is true negatives and FN is false negatives.

In this case, PPV = 130 / (130 + 60) = 130/190.

(Choices A and E) Sensitivity is a test's ability to correctly identify individuals with the disease. Sensitivity = TP / (TP + FN) = 130 / (130 + 50) = 130/180. Specificity is a test's ability to correctly identify individuals without the disease. Specificity = TN / (TN + FP) = 760 / (760 + 60) = 760/820.

(Choice C) The total number of individuals who have tuberculosis (based on the gold standard of positive sputum culture) is 180. The total number of individuals in this sample is 1000. Therefore, the prevalence of tuberculosis in this sample is 180/1000.

(Choice D) NPV = 760 / (760 + 50) = 760/810.

Educational objective:

The positive predictive value (PPV) of a test answers the question: If the test result is positive, what is the probability that a patient has the disease? PPV = true positives / (true positives + false positives).

Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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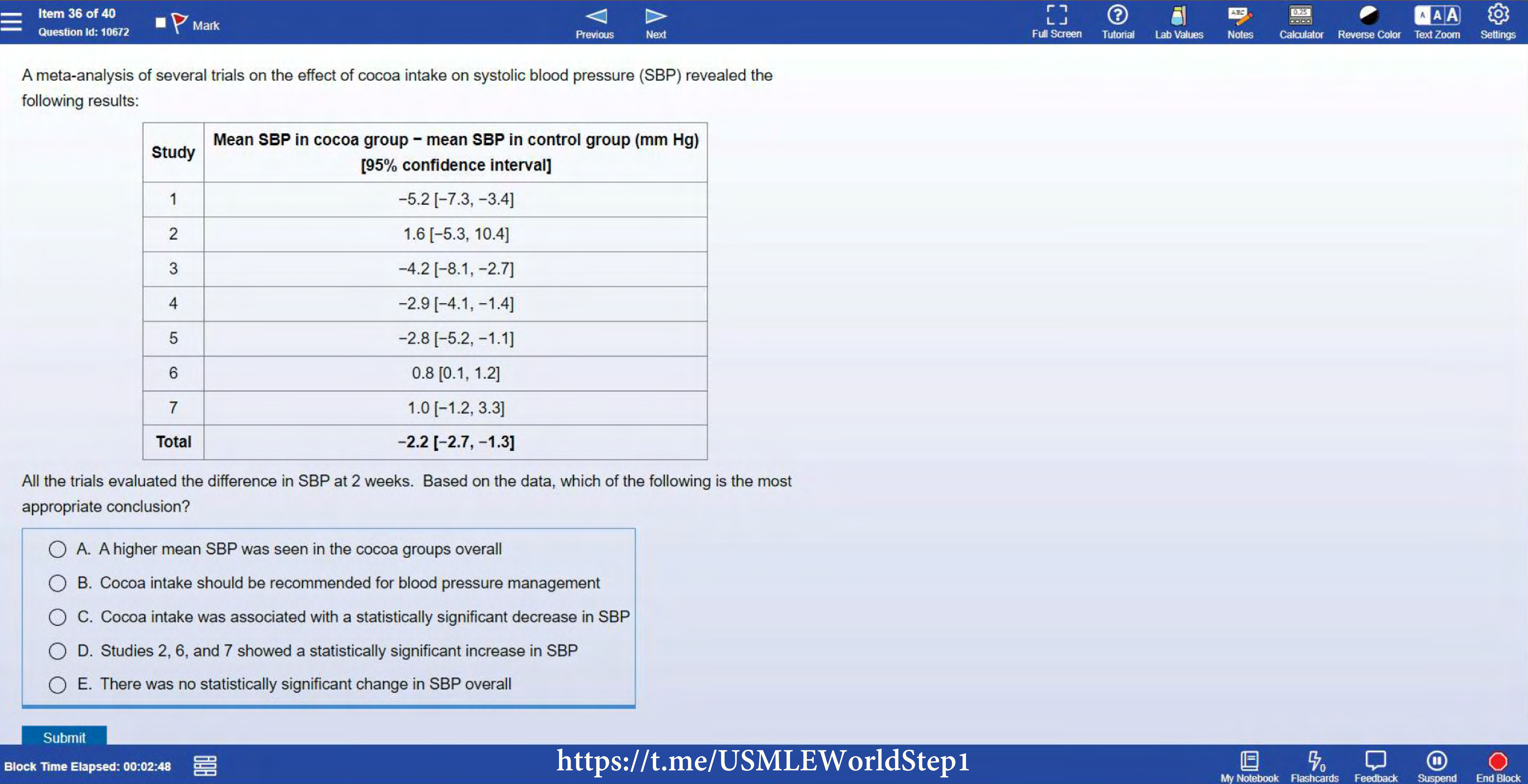
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A meta-analysis of several trials on the effect of cocoa intake on systolic blood pressure (SBP) revealed the following results:

Study	Mean SBP in cocoa group − mean SBP in control group (mm Hg) [95% confidence interval]
1	−5.2 [−7.3, −3.4]
2	1.6 [−5.3, 10.4]
3	−4.2 [−8.1, −2.7]
4	−2.9 [−4.1, −1.4]
5	−2.8 [−5.2, −1.1]
6	0.8 [0.1, 1.2]
7	1.0 [−1.2, 3.3]
Total	**−2.2 [−2.7, −1.3]**

All the trials evaluated the difference in SBP at 2 weeks. Based on the data, which of the following is the most appropriate conclusion?

○ A. A higher mean SBP was seen in the cocoa groups overall
○ B. Cocoa intake should be recommended for blood pressure management
○ C. Cocoa intake was associated with a statistically significant decrease in SBP
○ D. Studies 2, 6, and 7 showed a statistically significant increase in SBP
○ E. There was no statistically significant change in SBP overall

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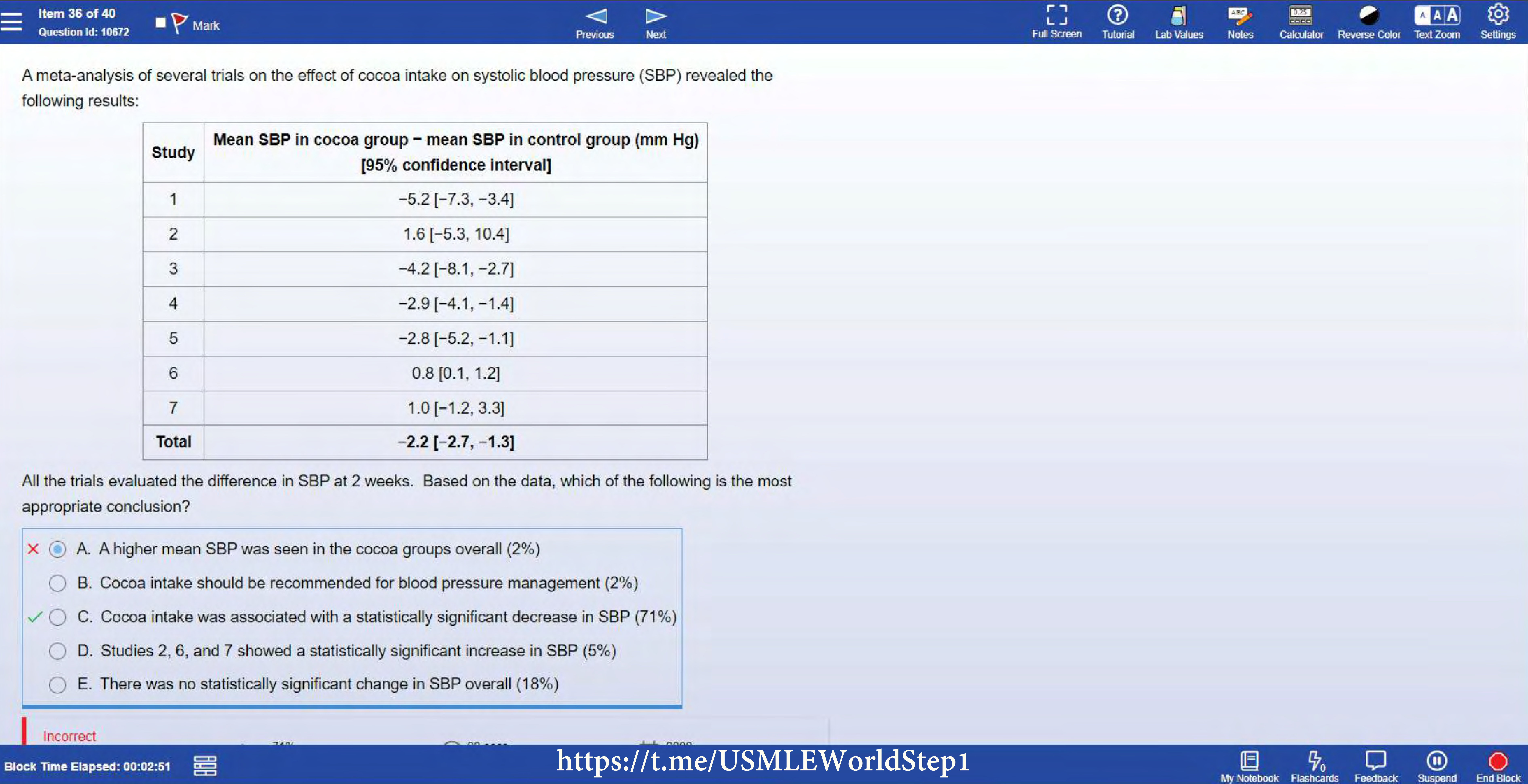
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A meta-analysis of several trials on the effect of cocoa intake on systolic blood pressure (SBP) revealed the following results:

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1	−5.2 [−7.3, −3.4]
2	1.6 [−5.3, 10.4]
3	−4.2 [−8.1, −2.7]
4	−2.9 [−4.1, −1.4]
5	−2.8 [−5.2, −1.1]
6	0.8 [0.1, 1.2]
7	1.0 [−1.2, 3.3]
Total	**−2.2 [−2.7, −1.3]**

All the trials evaluated the difference in SBP at 2 weeks. Based on the data, which of the following is the most appropriate conclusion?

- ✗ ● A. A higher mean SBP was seen in the cocoa groups overall (2%)
- ○ B. Cocoa intake should be recommended for blood pressure management (2%)
- ✓ ○ C. Cocoa intake was associated with a statistically significant decrease in SBP (71%)
- ○ D. Studies 2, 6, and 7 showed a statistically significant increase in SBP (5%)
- ○ E. There was no statistically significant change in SBP overall (18%)

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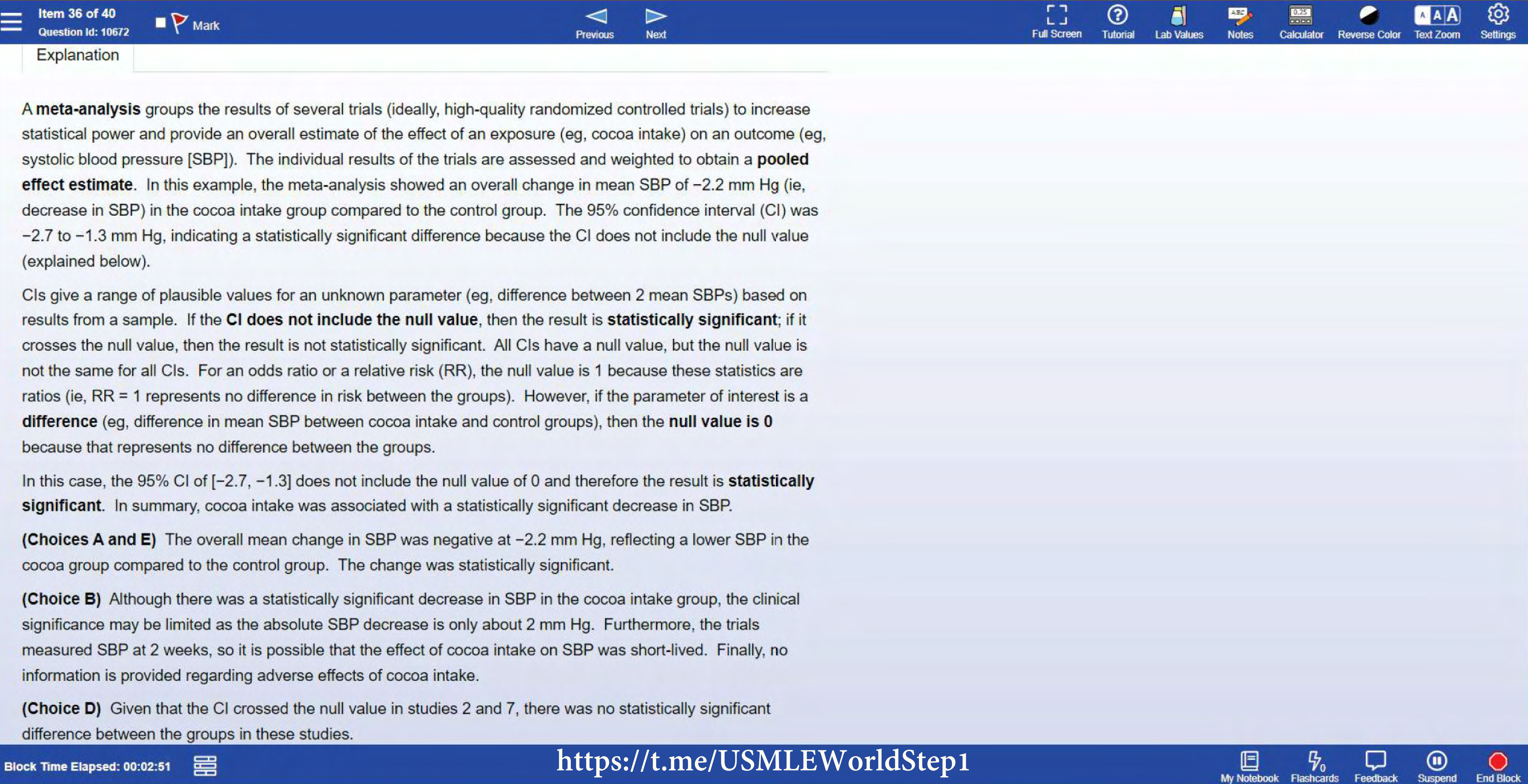


A **meta-analysis** groups the results of several trials (ideally, high-quality randomized controlled trials) to increase statistical power and provide an overall estimate of the effect of an exposure (eg, cocoa intake) on an outcome (eg, systolic blood pressure [SBP]). The individual results of the trials are assessed and weighted to obtain a **pooled effect estimate**. In this example, the meta-analysis showed an overall change in mean SBP of −2.2 mm Hg (ie, decrease in SBP) in the cocoa intake group compared to the control group. The 95% confidence interval (CI) was −2.7 to −1.3 mm Hg, indicating a statistically significant difference because the CI does not include the null value (explained below).

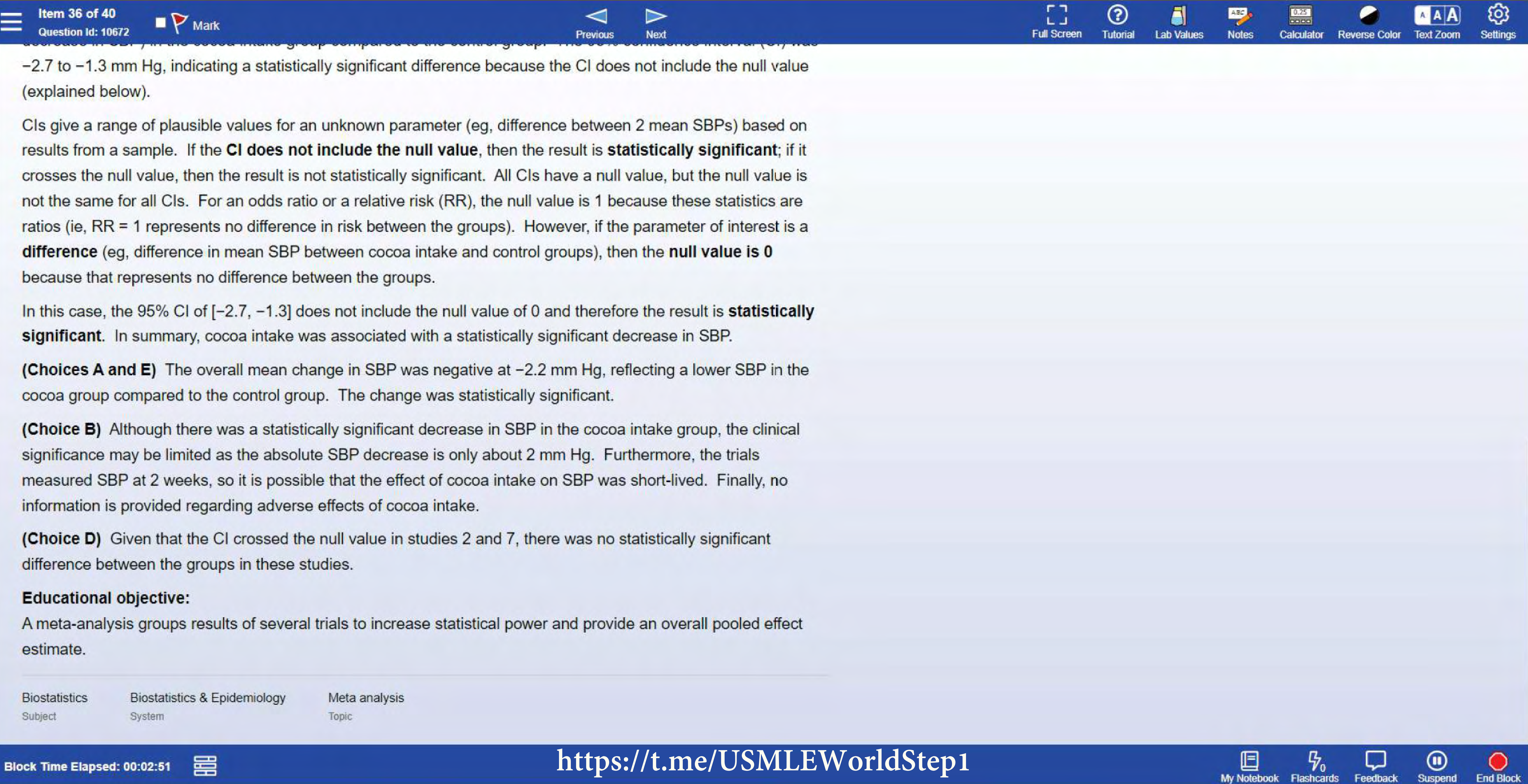
CIs give a range of plausible values for an unknown parameter (eg, difference between 2 mean SBPs) based on results from a sample. If the **CI does not include the null value**, then the result is **statistically significant**; if it crosses the null value, then the result is not statistically significant. All CIs have a null value, but the null value is not the same for all CIs. For an odds ratio or a relative risk (RR), the null value is 1 because these statistics are ratios (ie, RR = 1 represents no difference in risk between the groups). However, if the parameter of interest is a **difference** (eg, difference in mean SBP between cocoa intake and control groups), then the **null value is 0** because that represents no difference between the groups.

In this case, the 95% CI of [−2.7, −1.3] does not include the null value of 0 and therefore the result is **statistically significant**. In summary, cocoa intake was associated with a statistically significant decrease in SBP.

(Choices A and E) The overall mean change in SBP was negative at −2.2 mm Hg, reflecting a lower SBP in the cocoa group compared to the control group. The change was statistically significant.

(Choice B) Although there was a statistically significant decrease in SBP in the cocoa intake group, the clinical significance may be limited as the absolute SBP decrease is only about 2 mm Hg. Furthermore, the trials measured SBP at 2 weeks, so it is possible that the effect of cocoa intake on SBP was short-lived. Finally, no information is provided regarding adverse effects of cocoa intake.

(Choice D) Given that the CI crossed the null value in studies 2 and 7, there was no statistically significant difference between the groups in these studies.



decrease in SBP) in the cocoa intake group compared to the control group. The 95% confidence interval (CI) was −2.7 to −1.3 mm Hg, indicating a statistically significant difference because the CI does not include the null value (explained below).

CIs give a range of plausible values for an unknown parameter (eg, difference between 2 mean SBPs) based on results from a sample. If the **CI does not include the null value**, then the result is **statistically significant**; if it crosses the null value, then the result is not statistically significant. All CIs have a null value, but the null value is not the same for all CIs. For an odds ratio or a relative risk (RR), the null value is 1 because these statistics are ratios (ie, RR = 1 represents no difference in risk between the groups). However, if the parameter of interest is a **difference** (eg, difference in mean SBP between cocoa intake and control groups), then the **null value is 0** because that represents no difference between the groups.

In this case, the 95% CI of [−2.7, −1.3] does not include the null value of 0 and therefore the result is **statistically significant**. In summary, cocoa intake was associated with a statistically significant decrease in SBP.

(Choices A and E) The overall mean change in SBP was negative at −2.2 mm Hg, reflecting a lower SBP in the cocoa group compared to the control group. The change was statistically significant.

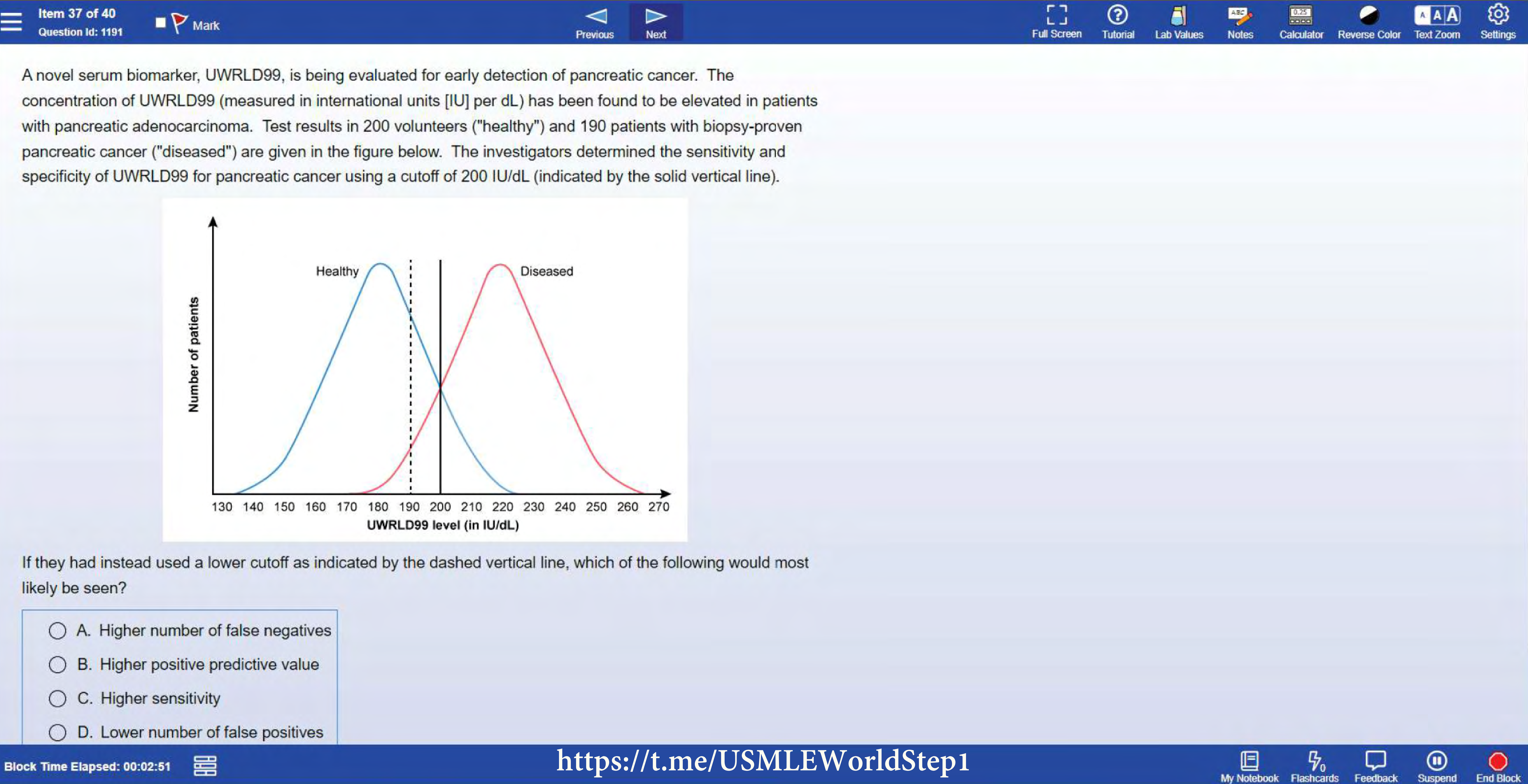
(Choice B) Although there was a statistically significant decrease in SBP in the cocoa intake group, the clinical significance may be limited as the absolute SBP decrease is only about 2 mm Hg. Furthermore, the trials measured SBP at 2 weeks, so it is possible that the effect of cocoa intake on SBP was short-lived. Finally, no information is provided regarding adverse effects of cocoa intake.

(Choice D) Given that the CI crossed the null value in studies 2 and 7, there was no statistically significant difference between the groups in these studies.

Educational objective:

A meta-analysis groups results of several trials to increase statistical power and provide an overall pooled effect estimate.

Biostatistics	Biostatistics & Epidemiology	Meta analysis
Subject	System	Topic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A novel serum biomarker, UWRLD99, is being evaluated for early detection of pancreatic cancer. The concentration of UWRLD99 (measured in international units [IU] per dL) has been found to be elevated in patients with pancreatic adenocarcinoma. Test results in 200 volunteers ("healthy") and 190 patients with biopsy-proven pancreatic cancer ("diseased") are given in the figure below. The investigators determined the sensitivity and specificity of UWRLD99 for pancreatic cancer using a cutoff of 200 IU/dL (indicated by the solid vertical line).

Healthy
Diseased
Number of patients
130 140 150 160 170 180 190 200 210 220 230 240 250 260 270
UWRLD99 level (in IU/dL)

If they had instead used a lower cutoff as indicated by the dashed vertical line, which of the following would most likely be seen?

○ A. Higher number of false negatives
○ B. Higher positive predictive value
○ C. Higher sensitivity
○ D. Lower number of false positives

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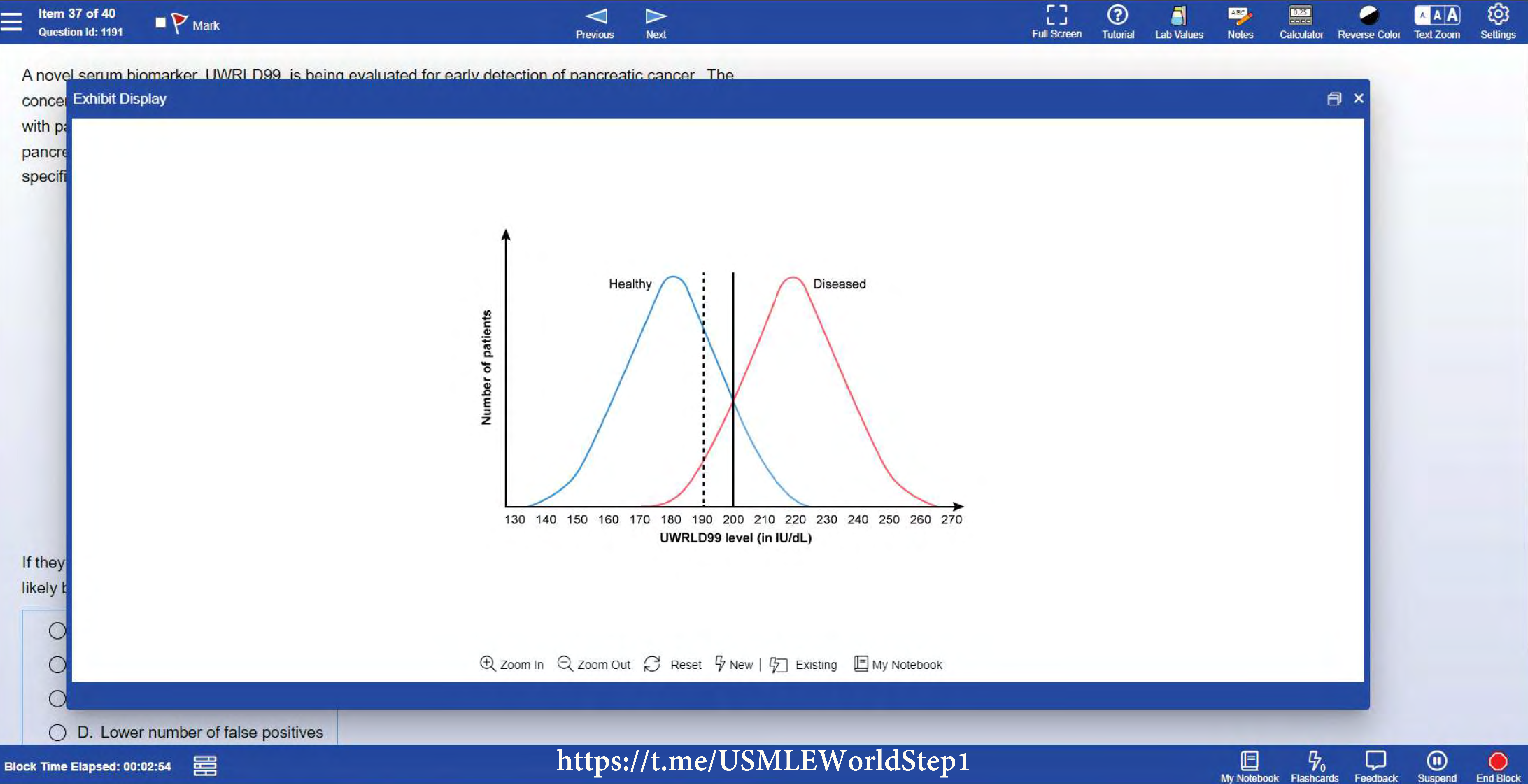
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Exhibit Display
Healthy
Diseased
Number of patients
130
140
150
160
170
180
190
200
210
220
230
240
250
260
270
UWRLD99 level (in IU/dL)
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A novel serum biomarker UWRLD99 is being evaluated for early detection of pancreatic cancer The

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○ D. Lower number of false positives

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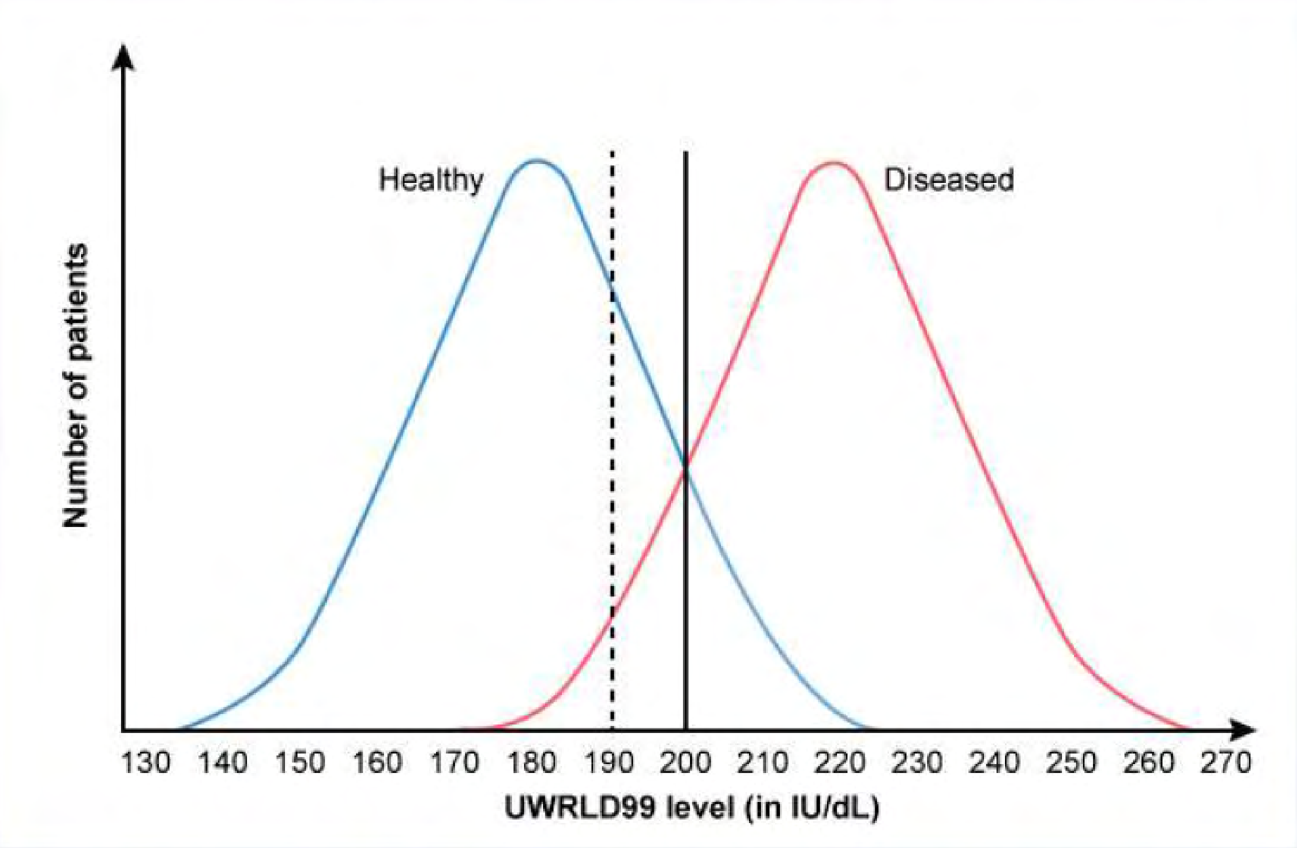
pancreatic cancer ("diseased") are given in the figure below. The investigators determined the sensitivity and specificity of UWRLD99 for pancreatic cancer using a cutoff of 200 IU/dL (indicated by the solid vertical line).



If they had instead used a lower cutoff as indicated by the dashed vertical line, which of the following would most likely be seen?

- ○ A. Higher number of false negatives
- ○ B. Higher positive predictive value
- ○ C. Higher sensitivity
- ○ D. Lower number of false positives
- ○ E. Lower number of true positives

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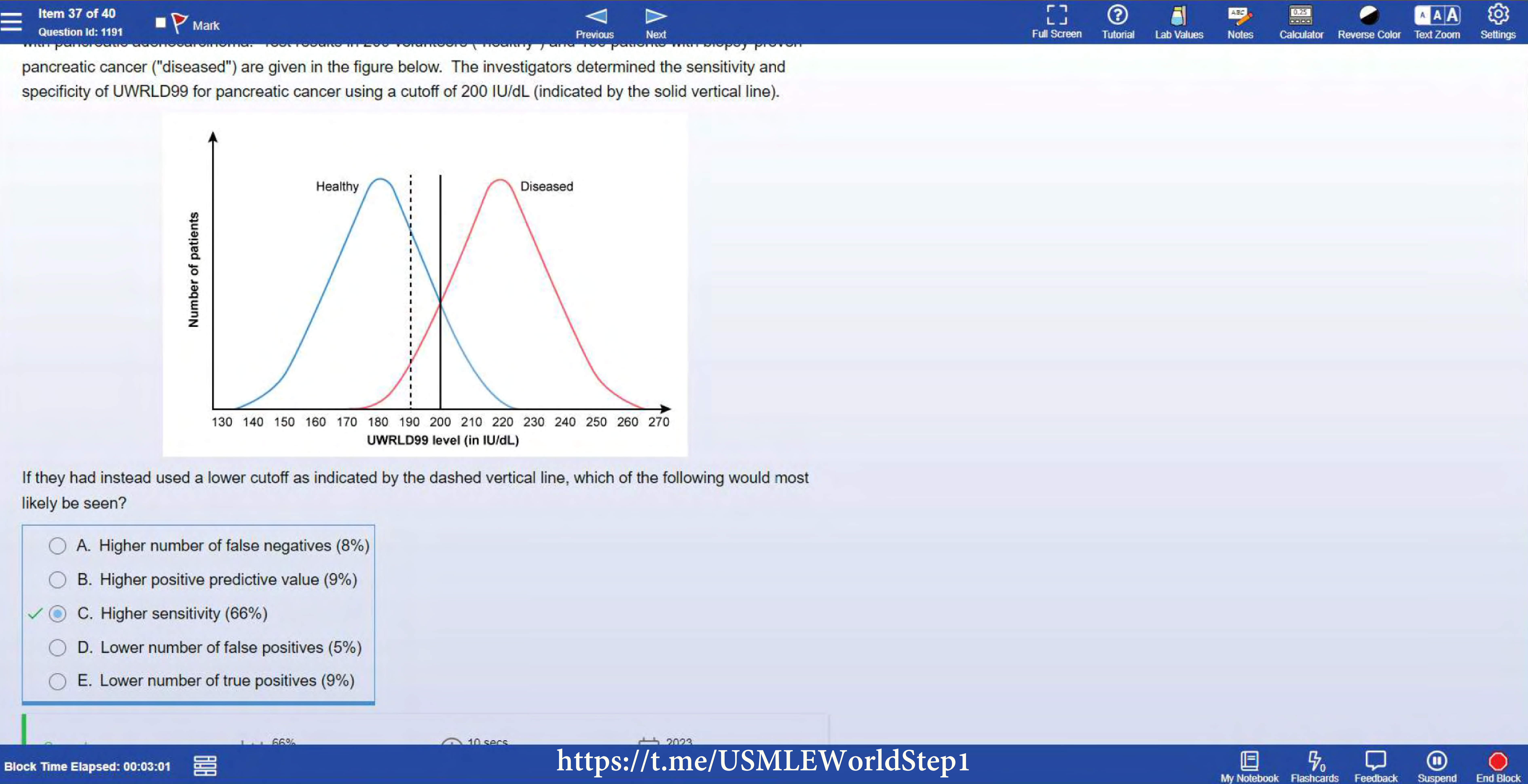
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with pancreatic adenocarcinoma. Test results in 200 volunteers ("healthy") and 100 patients with biopsy-proven pancreatic cancer ("diseased") are given in the figure below. The investigators determined the sensitivity and specificity of UWRLD99 for pancreatic cancer using a cutoff of 200 IU/dL (indicated by the solid vertical line).

Healthy
Diseased
Number of patients
130
140
150
160
170
180
190
200
210
220
230
240
250
260
270
UWRLD99 level (in IU/dL)

If they had instead used a lower cutoff as indicated by the dashed vertical line, which of the following would most likely be seen?

- ○ A. Higher number of false negatives (8%)
- ○ B. Higher positive predictive value (9%)
- ✓ ● C. Higher sensitivity (66%)
- ○ D. Lower number of false positives (5%)
- ○ E. Lower number of true positives (9%)

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Explanation

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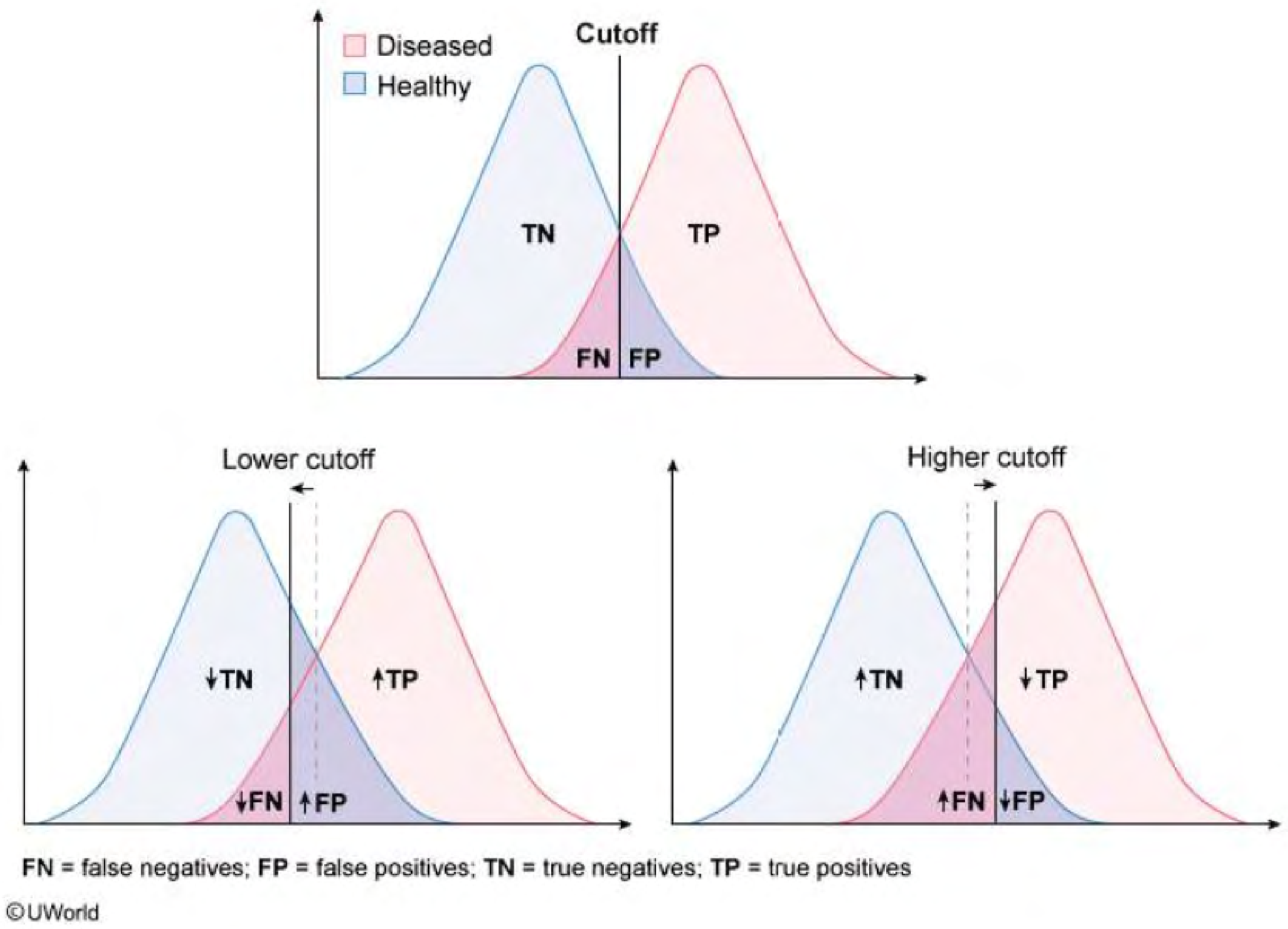
Diseased
Healthy
Cutoff
TN
TP
FN
FP
Lower cutoff
↓TN
↑TP
↓FN
↑FP
Higher cutoff
↑TN
↓TP
↑FN
↓FP

FN = false negatives; FP = false positives; TN = true negatives; TP = true positives

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sensitive test, most diseased patients will have a positive test result (and a **n**egative test result would help rule

FN = false negatives; **FP** = false positives; **TN** = true negatives; **TP** = true positives

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Important parameters of diagnostic tests include the following:

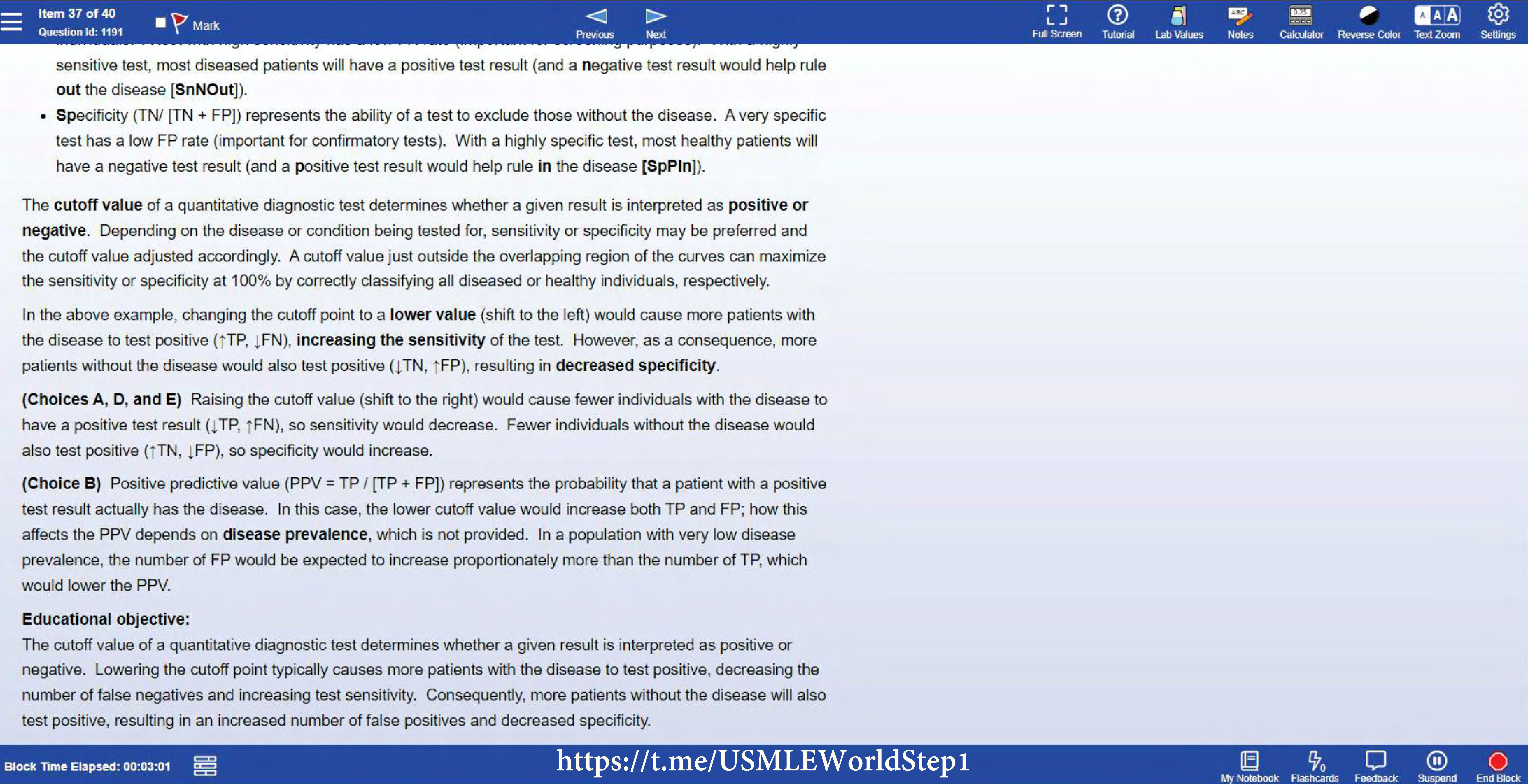
- True positives (TP) represent diseased individuals with positive test results.
- True negatives (TN) represent healthy individuals with negative test results.
- False positives (FP) represent healthy individuals with positive test results.
- False negatives (FN) represent diseased individuals with negative test results.
- **Sn**sitivity (TP/ [TP + FN]) represents a test's ability to correctly identify diseased individuals from among all individuals. A test with high sensitivity has a low FN rate (important for screening purposes). With a highly sensitive test, most diseased patients will have a positive test result (and a **n**egative test result would help rule **out** the disease [**SnNOut**]).
- **Sp**ecificity (TN/ [TN + FP]) represents the ability of a test to exclude those without the disease. A very specific test has a low FP rate (important for confirmatory tests). With a highly specific test, most healthy patients will have a negative test result (and a **p**ositive test result would help rule **in** the disease [**SpPIn**]).

The **cutoff value** of a quantitative diagnostic test determines whether a given result is interpreted as **positive or negative**. Depending on the disease or condition being tested for, sensitivity or specificity may be preferred and the cutoff value adjusted accordingly. A cutoff value just outside the overlapping region of the curves can maximize the sensitivity or specificity at 100% by correctly classifying all diseased or healthy individuals, respectively.

In the above example, changing the cutoff point to a **lower value** (shift to the left) would cause more patients with the disease to test positive (↑TP, ↓FN), **increasing the sensitivity** of the test. However, as a consequence, more patients without the disease would also test positive (↓TN, ↑FP), resulting in **decreased specificity**.

(Choices A, D, and E) Raising the cutoff value (shift to the right) would cause fewer individuals with the disease to have a positive test result (↓TP, ↑FN), so sensitivity would decrease. Fewer individuals without the disease would also test positive (↑TN, ↓FP), so specificity would increase.

(Choice B) Positive predictive value (PPV = TP / [TP + FP]) represents the probability that a patient with a positive



sensitive test, most diseased patients will have a positive test result (and a **n**egative test result would help rule **out** the disease [**SnNOut**]).

- **Sp**ecificity (TN/ [TN + FP]) represents the ability of a test to exclude those without the disease. A very specific test has a low FP rate (important for confirmatory tests). With a highly specific test, most healthy patients will have a negative test result (and a **p**ositive test result would help rule **in** the disease [**SpPIn**]).

The **cutoff value** of a quantitative diagnostic test determines whether a given result is interpreted as **positive or negative**. Depending on the disease or condition being tested for, sensitivity or specificity may be preferred and the cutoff value adjusted accordingly. A cutoff value just outside the overlapping region of the curves can maximize the sensitivity or specificity at 100% by correctly classifying all diseased or healthy individuals, respectively.

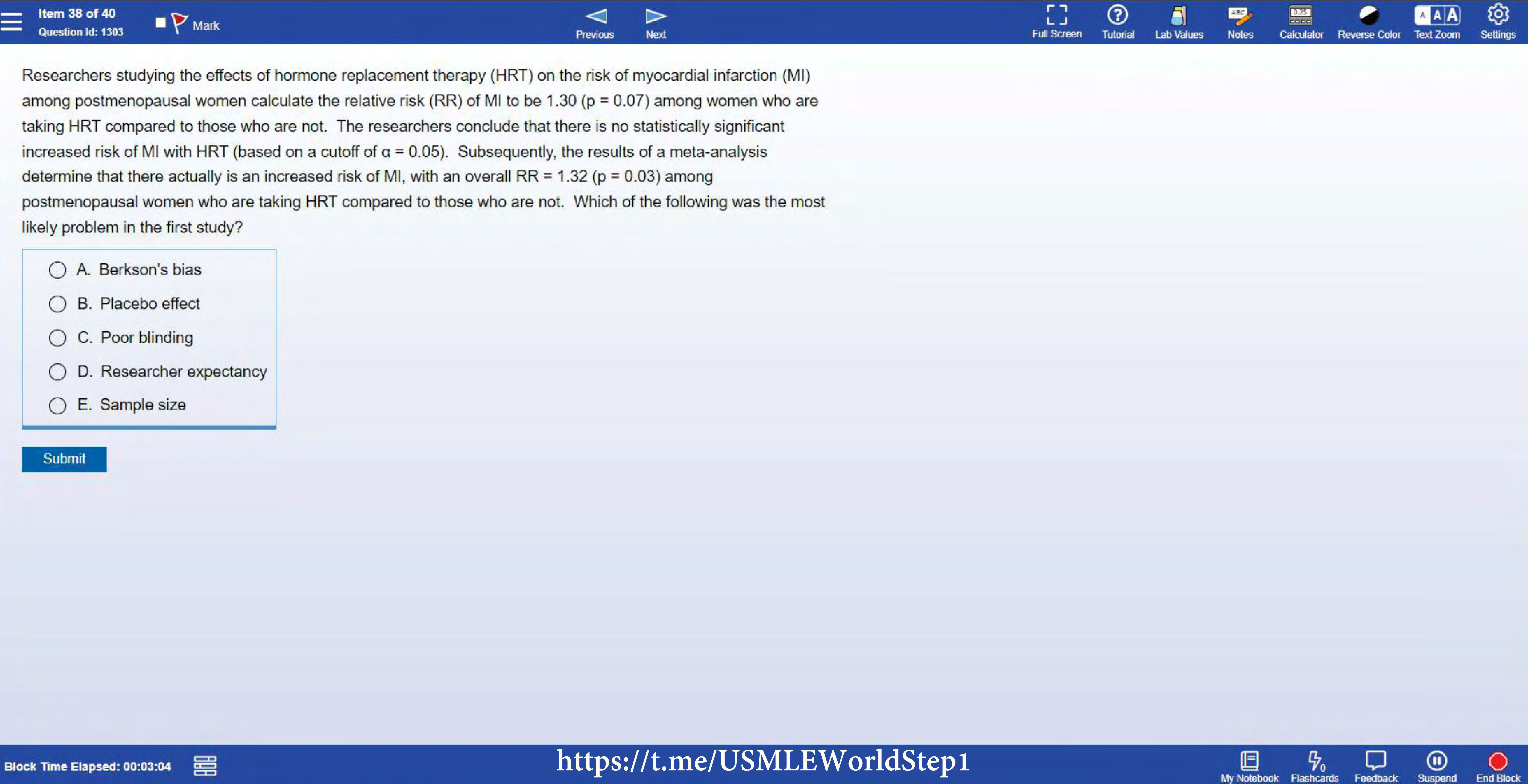
In the above example, changing the cutoff point to a **lower value** (shift to the left) would cause more patients with the disease to test positive (↑TP, ↓FN), **increasing the sensitivity** of the test. However, as a consequence, more patients without the disease would also test positive (↓TN, ↑FP), resulting in **decreased specificity**.

(Choices A, D, and E) Raising the cutoff value (shift to the right) would cause fewer individuals with the disease to have a positive test result (↓TP, ↑FN), so sensitivity would decrease. Fewer individuals without the disease would also test positive (↑TN, ↓FP), so specificity would increase.

(Choice B) Positive predictive value (PPV = TP / [TP + FP]) represents the probability that a patient with a positive test result actually has the disease. In this case, the lower cutoff value would increase both TP and FP; how this affects the PPV depends on **disease prevalence**, which is not provided. In a population with very low disease prevalence, the number of FP would be expected to increase proportionately more than the number of TP, which would lower the PPV.

Educational objective:

The cutoff value of a quantitative diagnostic test determines whether a given result is interpreted as positive or negative. Lowering the cutoff point typically causes more patients with the disease to test positive, decreasing the number of false negatives and increasing test sensitivity. Consequently, more patients without the disease will also test positive, resulting in an increased number of false positives and decreased specificity.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Researchers studying the effects of hormone replacement therapy (HRT) on the risk of myocardial infarction (MI) among postmenopausal women calculate the relative risk (RR) of MI to be 1.30 ($p = 0.07$) among women who are taking HRT compared to those who are not. The researchers conclude that there is no statistically significant increased risk of MI with HRT (based on a cutoff of $\alpha = 0.05$). Subsequently, the results of a meta-analysis determine that there actually is an increased risk of MI, with an overall RR = 1.32 ($p = 0.03$) among postmenopausal women who are taking HRT compared to those who are not. Which of the following was the most likely problem in the first study?

○ A. Berkson's bias
○ B. Placebo effect
○ C. Poor blinding
○ D. Researcher expectancy
○ E. Sample size

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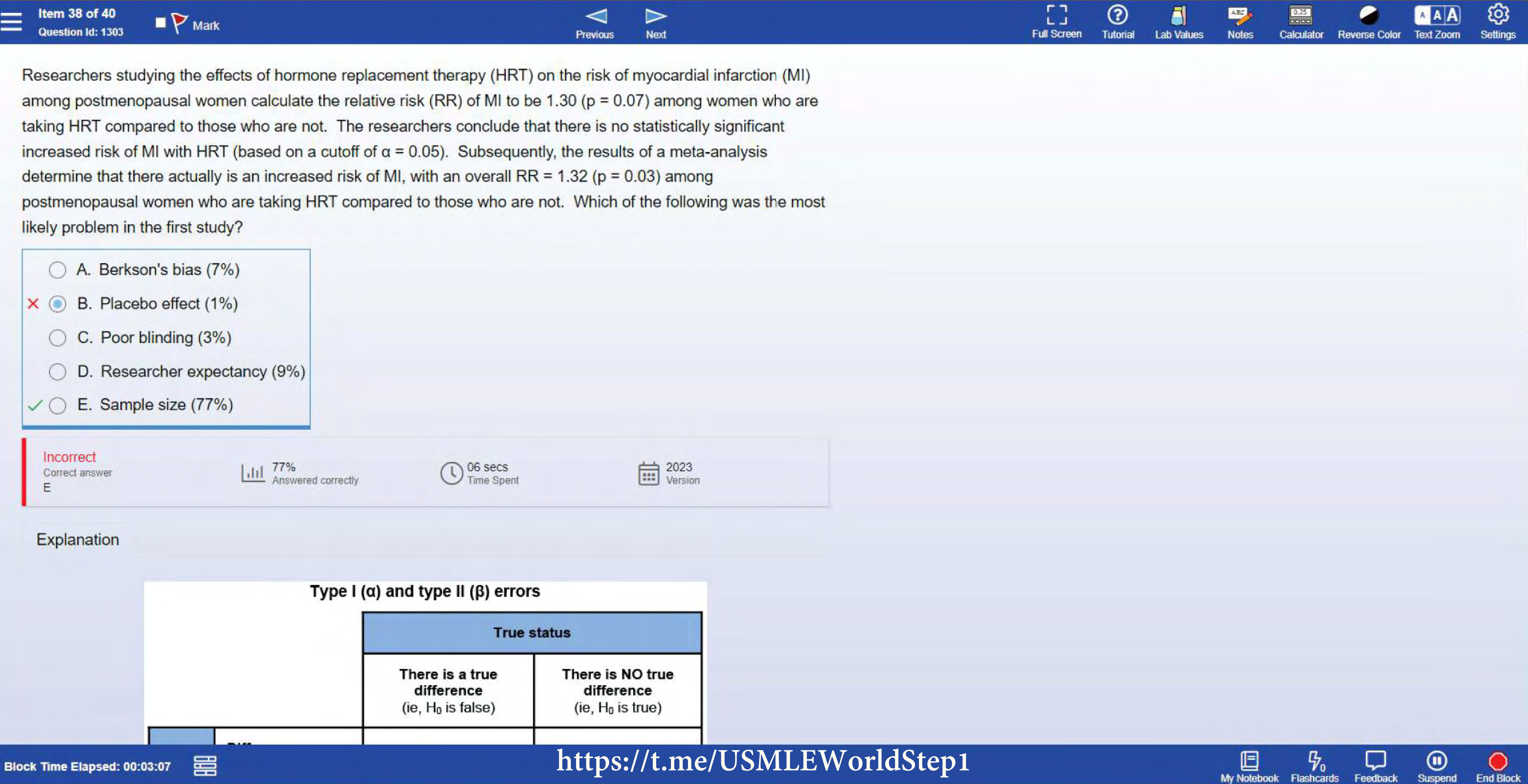
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- ○ A. Berkson's bias (7%)
- ✗ ● B. Placebo effect (1%)
- ○ C. Poor blinding (3%)
- ○ D. Researcher expectancy (9%)
- ✓ ○ E. Sample size (77%)

Incorrect
Correct answer
E

77%
Answered correctly

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Explanation

Type I (α) and type II (β) errors

	True status	
	There is a true difference (ie, H_0 is false)	**There is NO true difference** (ie, H_0 is true)

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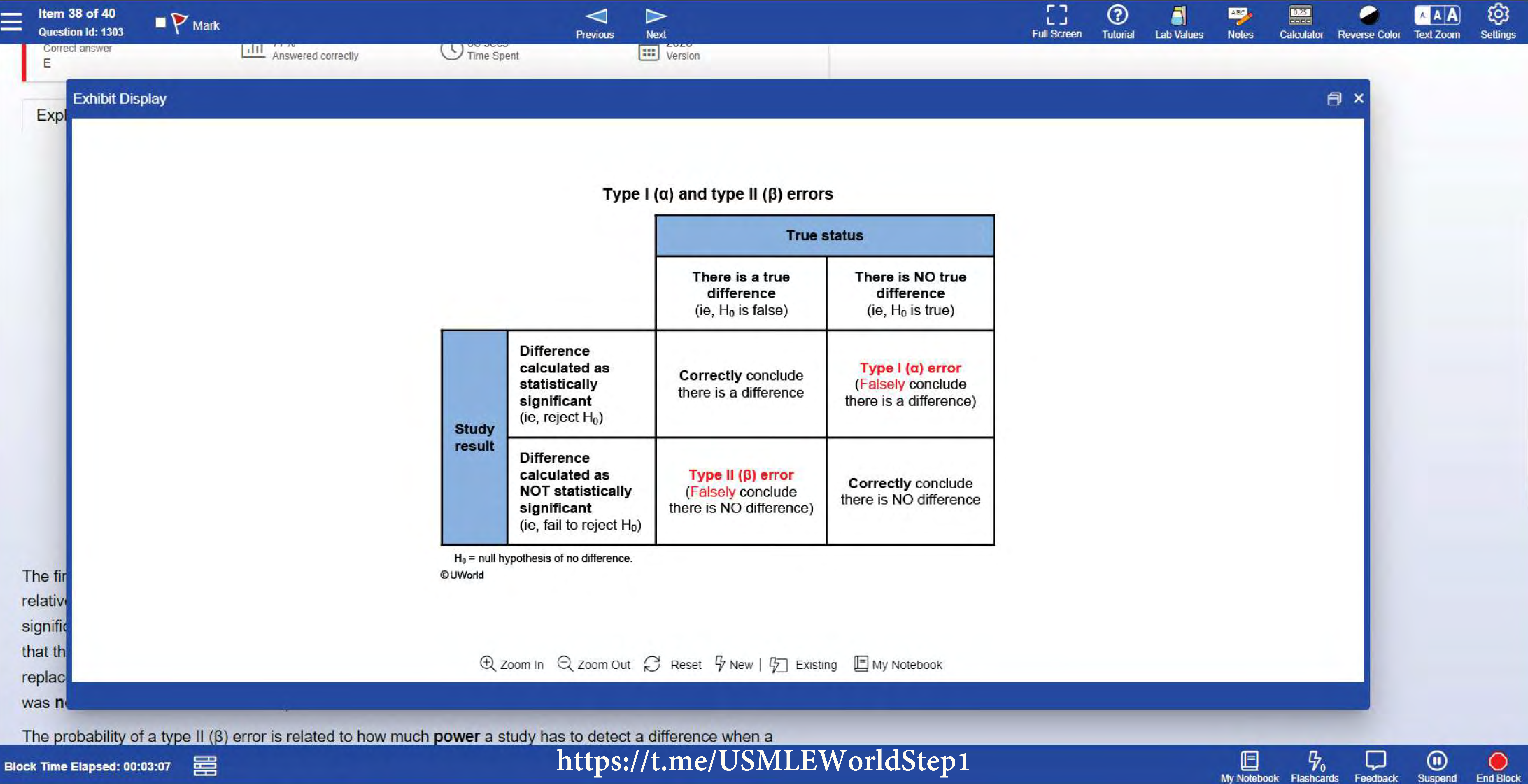
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Correct answer
E

Answered correctly

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Type I (α) and type II (β) errors

		True status	
		There is a true difference (ie, H_0 is false)	**There is NO true difference** (ie, H_0 is true)
Study result	**Difference calculated as statistically significant** (ie, reject H_0)	**Correctly** conclude there is a difference	**Type I (α) error** (Falsely conclude there is a difference)
	Difference calculated as NOT statistically significant (ie, fail to reject H_0)	**Type II (β) error** (Falsely conclude there is NO difference)	**Correctly** conclude there is NO difference

H_0 = null hypothesis of no difference.

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The probability of a type II (β) error is related to how much **power** a study has to detect a difference when a

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The first study and the meta-analysis (combined results of several studies) had similar outcomes in terms of relative risk (RR); however, they arrived at different conclusions because the p-value reached statistical significance ($p < \alpha = 0.05$) in the meta-analysis but not in the first study. The most probable reason behind this is that the **larger** meta-analysis reflects the true status (increased risk of myocardial infarction [MI] with hormone replacement therapy [HRT]), whereas the first study result represented a **type II (β) error** (**falsely** concluded there was **no** increased risk of MI with HRT).

The probability of a type II (β) error is related to how much **power** a study has to detect a difference when a difference actually exists (power = 1 – β). **Sample size** and power are related in that studies with a larger sample size have greater power to detect differences if these exist. The small sample size of the first study made it underpowered to detect a difference in outcome between patients who were treated with HRT and those who were not.

The sample size did not change the value of α (typically set at 0.05). However, because the first study was underpowered, the p-value obtained was not statistically significant ($p = 0.07 > \alpha = 0.05$), leading to a false conclusion of no increased risk of MI with HRT.

(Choice A) Berkson's bias refers to selection bias that can be created by selecting hospitalized patients as the control group.

(Choice B) Placebo effect refers to patients' expectations affecting an outcome. However, in this case, the control group is taking neither HRT nor a placebo medication.

(Choices C and D) Given that the RR obtained in the first study was similar to the one obtained in the meta-analysis (1.32 versus 1.30), it is unlikely that design flaws (eg, poor blinding, researcher expectancy) were present in the study.

Educational objective:
A study's power increases as its sample size increases. Therefore, the larger the sample, the greater the ability of a study to detect a difference when one truly exists.

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A research group conducted a study to compare the levels of creatine kinase-MB (CK-MB) between type 2 diabetes mellitus (T2DM) patients given statin therapy. Participants were divided into 4 groups based on treatment. Groups I, II, and III consisted of T2DM patients who had been given statin therapy (atorvastatin, simvastatin, rosuvastatin, respectively) for at least 6 months. Group IV consisted of T2DM patients who had not been given statin therapy. Which of the following statistical tests is most appropriate to compare the CK-MB levels between Groups I, II, III, and IV in this study?

- ○ A. Analysis of variance
- ○ B. Chi-square test
- ○ C. Independent *t*-test
- ○ D. Paired *t*-test
- ○ E. Correlation analysis

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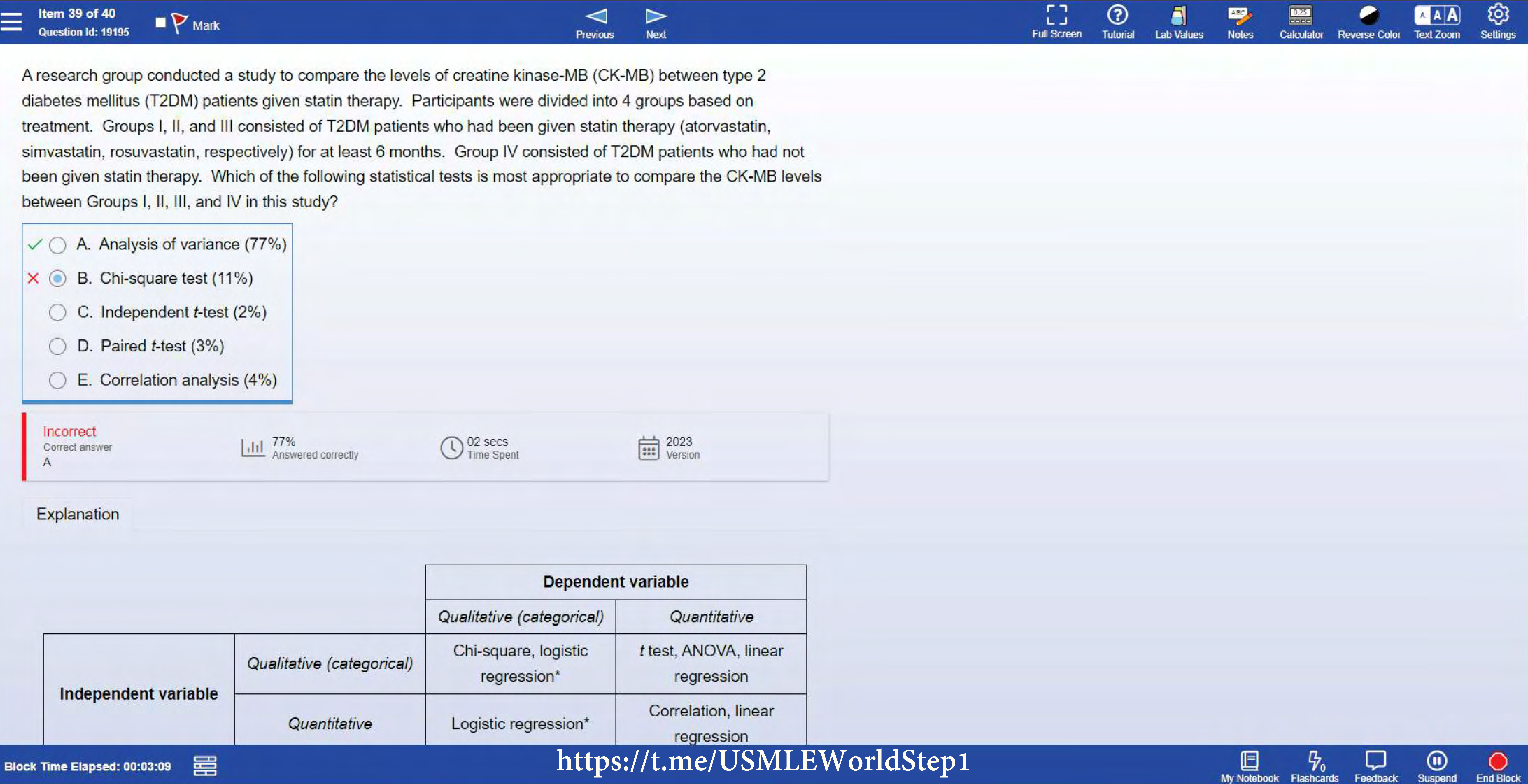
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- ✓ ○ A. Analysis of variance (77%)
- ✗ ● B. Chi-square test (11%)
- ○ C. Independent *t*-test (2%)
- ○ D. Paired *t*-test (3%)
- ○ E. Correlation analysis (4%)

Incorrect
Correct answer
A

77%
Answered correctly

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Explanation

		Dependent variable	
		Qualitative (categorical)	*Quantitative*
Independent variable	*Qualitative (categorical)*	Chi-square, logistic regression*	*t* test, ANOVA, linear regression
	Quantitative	Logistic regression*	Correlation, linear regression

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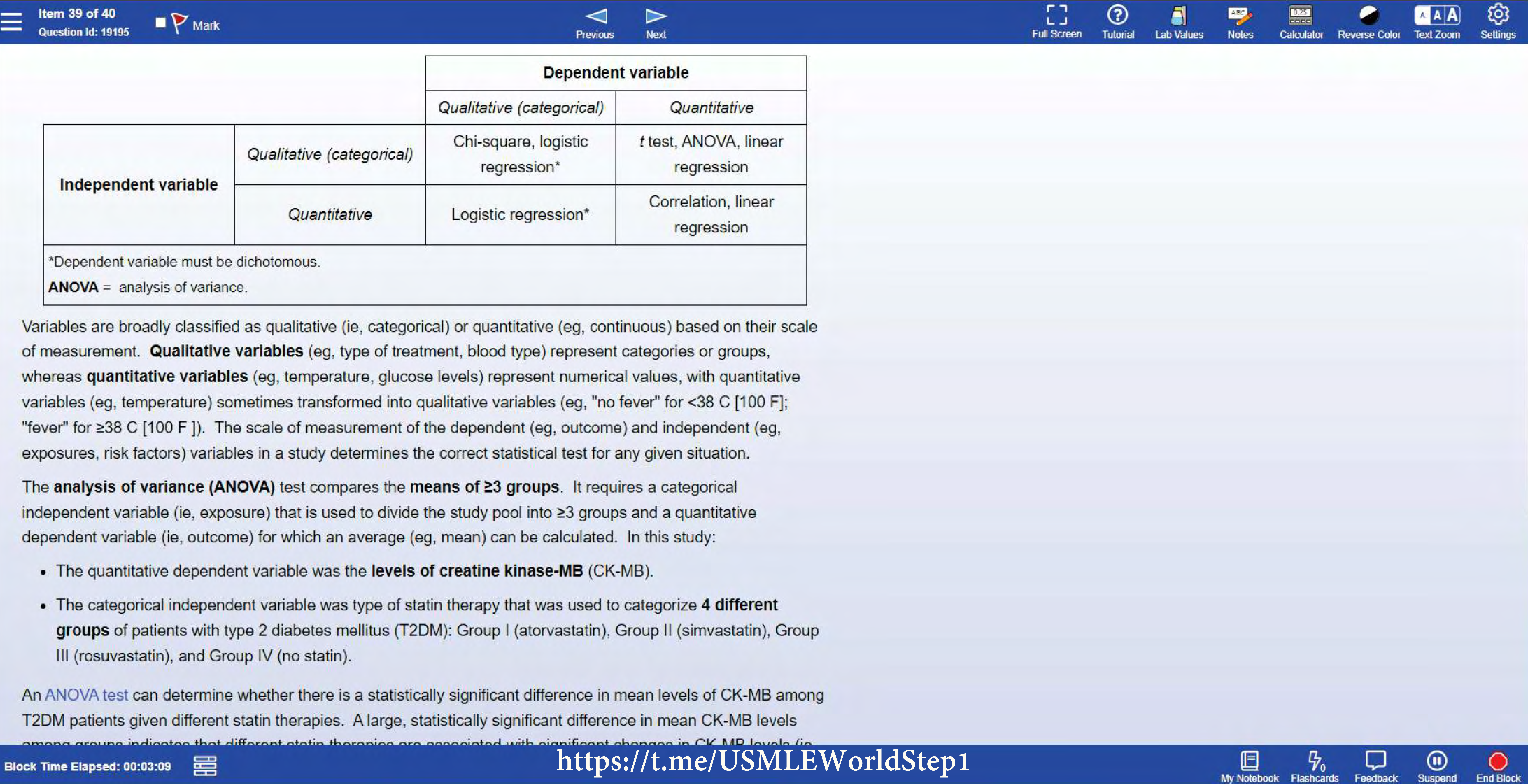

		Dependent variable	
		Qualitative (categorical)	*Quantitative*
Independent variable	*Qualitative (categorical)*	Chi-square, logistic regression*	*t* test, ANOVA, linear regression
	Quantitative	Logistic regression*	Correlation, linear regression

*Dependent variable must be dichotomous.

ANOVA = analysis of variance.

Variables are broadly classified as qualitative (ie, categorical) or quantitative (eg, continuous) based on their scale of measurement. **Qualitative variables** (eg, type of treatment, blood type) represent categories or groups, whereas **quantitative variables** (eg, temperature, glucose levels) represent numerical values, with quantitative variables (eg, temperature) sometimes transformed into qualitative variables (eg, "no fever" for <38 C [100 F]; "fever" for ≥38 C [100 F]). The scale of measurement of the dependent (eg, outcome) and independent (eg, exposures, risk factors) variables in a study determines the correct statistical test for any given situation.

The **analysis of variance (ANOVA)** test compares the **means of ≥3 groups**. It requires a categorical independent variable (ie, exposure) that is used to divide the study pool into ≥3 groups and a quantitative dependent variable (ie, outcome) for which an average (eg, mean) can be calculated. In this study:

- The quantitative dependent variable was the **levels of creatine kinase-MB** (CK-MB).
- The categorical independent variable was type of statin therapy that was used to categorize **4 different groups** of patients with type 2 diabetes mellitus (T2DM): Group I (atorvastatin), Group II (simvastatin), Group III (rosuvastatin), and Group IV (no statin).

An ANOVA test can determine whether there is a statistically significant difference in mean levels of CK-MB among T2DM patients given different statin therapies. A large, statistically significant difference in mean CK-MB levels among groups indicates that different statin therapies are associated with significant changes in CK-MB levels (ie,

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- The quantitative dependent variable was the **levels of creatine kinase-MB** (CK-MB).
- The categorical independent variable was type of statin therapy that was used to categorize **4 different groups** of patients with type 2 diabetes mellitus (T2DM): Group I (atorvastatin), Group II (simvastatin), Group III (rosuvastatin), and Group IV (no statin).

An ANOVA test can determine whether there is a statistically significant difference in mean levels of CK-MB among T2DM patients given different statin therapies. A large, statistically significant difference in mean CK-MB levels among groups indicates that different statin therapies are associated with significant changes in CK-MB levels (ie, the null hypothesis is rejected).

(Choice B) The chi-square test evaluates the association between 2 categorical variables, as in a study evaluating the association between sex (ie, "male" and "female") and myocardial infarction (ie, presence of myocardial infarction, absence of myocardial infarction).

(Choices C and D) The *t*-tests compare the mean of a quantitative variable *between 2 groups*. A paired *t*-test is used when the groups are dependent (eg, comparing mean blood pressure [quantitative variable] in the same group of patients before and after antihypertensive therapy). An independent *t*-test is used when the groups are independent (eg, comparing mean CK-MB levels [quantitative variable] between a group of patients given statin therapy and another not given statin therapy).

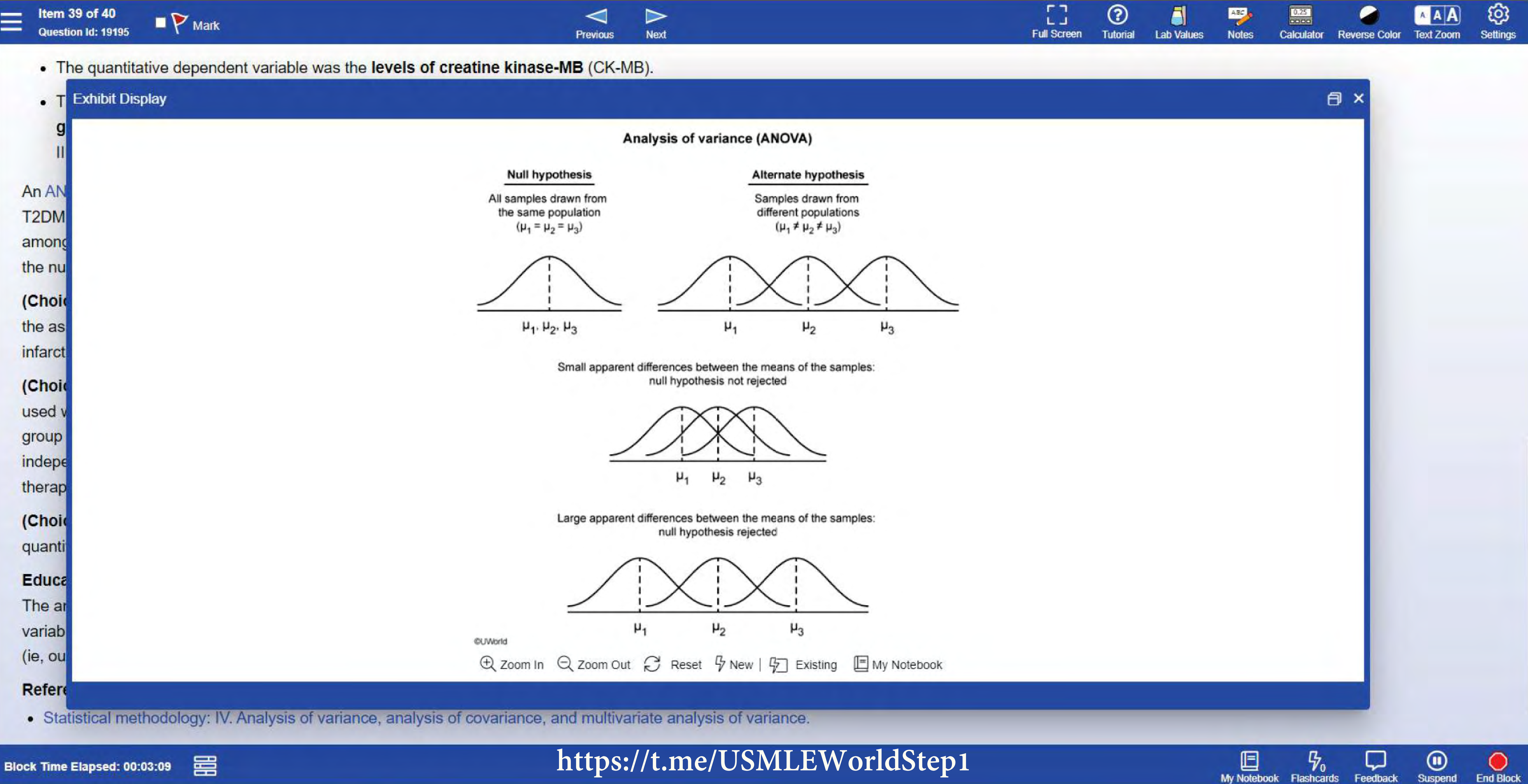
(Choice E) A correlation analysis uses the correlation coefficient to describe the linear relationship between 2 quantitative variables, as in a study evaluating the linear relationship between hours of sleep and irritability score.

Educational objective:

The analysis of variance test compares the means of ≥3 groups. The test requires a categorical independent variable (ie, exposure) that is used to divide the study pool into ≥3 groups and a quantitative dependent variable (ie, outcome) for which an average (eg, mean) can be calculated.

References

- Statistical methodology: IV. Analysis of variance, analysis of covariance, and multivariate analysis of variance.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- The quantitative dependent variable was the **levels of creatine kinase-MB** (CK-MB).
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Analysis of variance (ANOVA)

Null hypothesis

All samples drawn from
the same population
($\mu_1 = \mu_2 = \mu_3$)

Alternate hypothesis

Samples drawn from
different populations
($\mu_1 \neq \mu_2 \neq \mu_3$)

μ_1, μ_2, μ_3
μ_1
μ_2
μ_3

Small apparent differences between the means of the samples:
null hypothesis not rejected

Large apparent differences between the means of the samples:
null hypothesis rejected

μ_1
μ_2
μ_3
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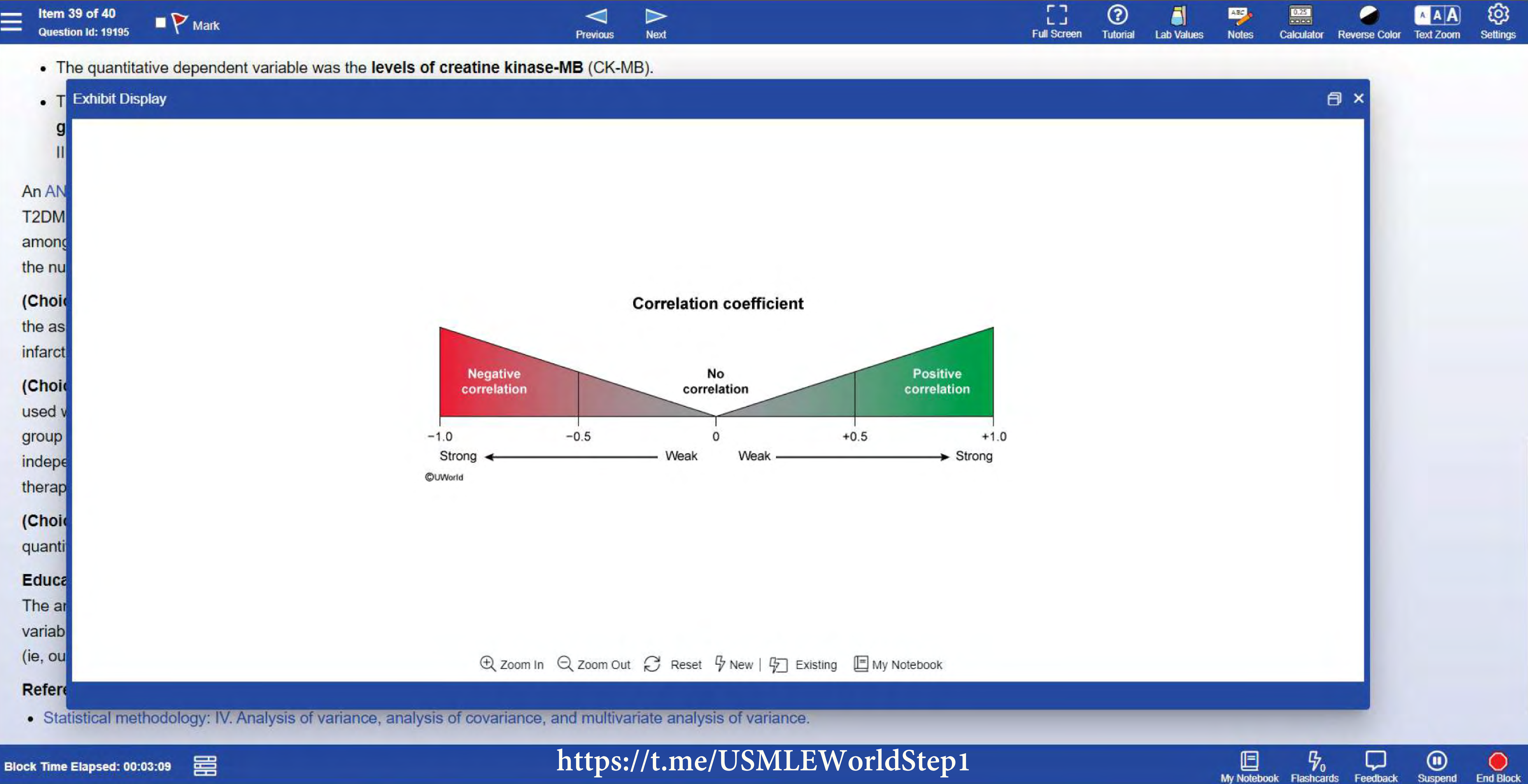
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Correlation coefficient
Negative correlation
No correlation
Positive correlation
−1.0
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0
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+1.0
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Weak
Weak
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- The quantitative dependent variable was the **levels of creatine kinase-MB** (CK-MB).
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- Statistical methodology: IV. Analysis of variance, analysis of covariance, and multivariate analysis of variance.

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- The quantitative dependent variable was the **levels of creatine kinase-MB** (CK-MB).
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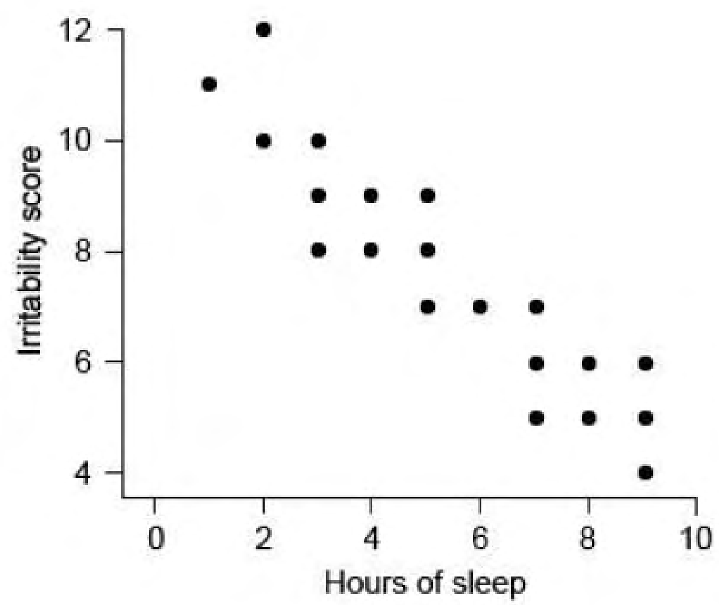

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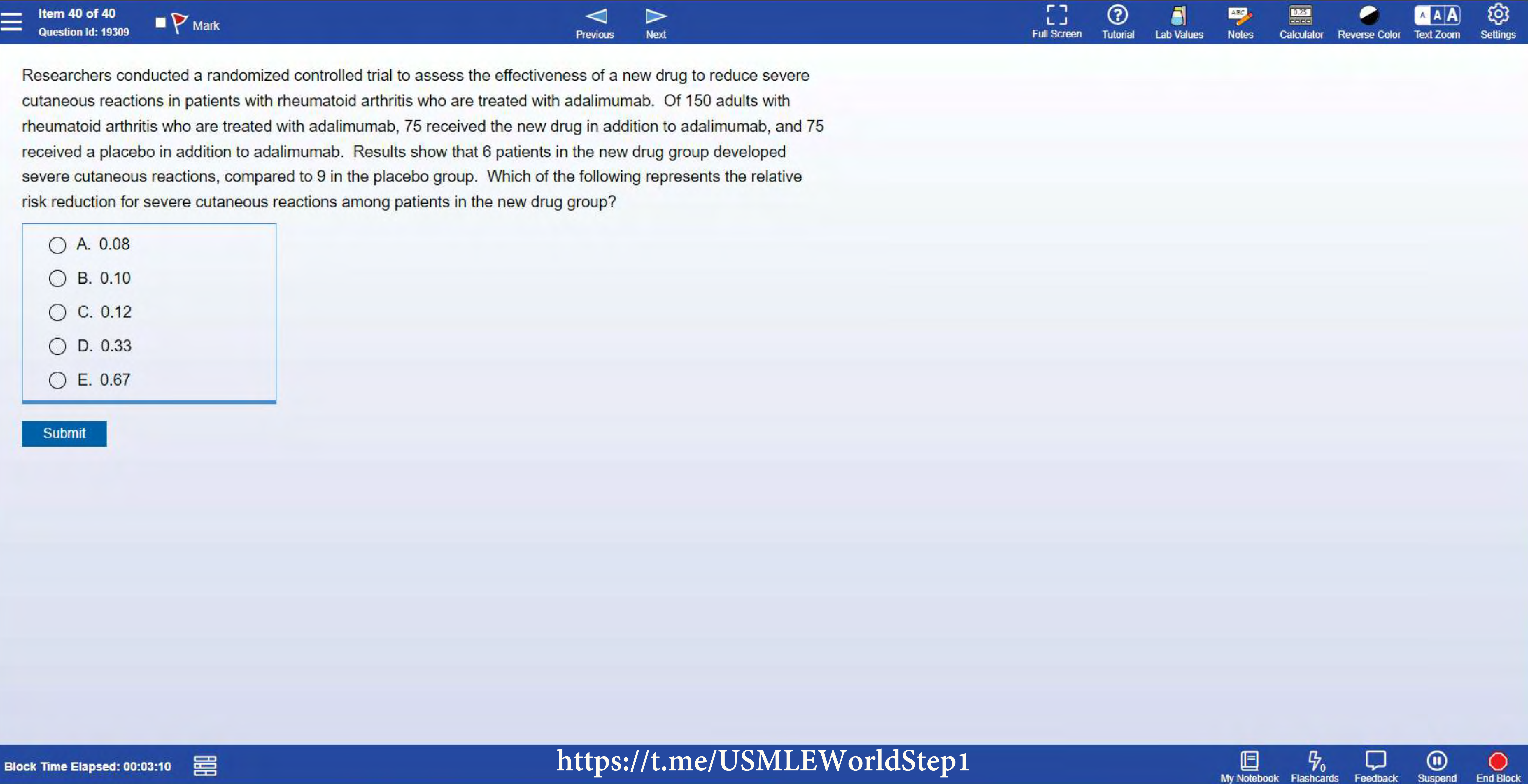
- Statistical methodology: IV. Analysis of variance, analysis of covariance, and multivariate analysis of variance.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Researchers conducted a randomized controlled trial to assess the effectiveness of a new drug to reduce severe cutaneous reactions in patients with rheumatoid arthritis who are treated with adalimumab. Of 150 adults with rheumatoid arthritis who are treated with adalimumab, 75 received the new drug in addition to adalimumab, and 75 received a placebo in addition to adalimumab. Results show that 6 patients in the new drug group developed severe cutaneous reactions, compared to 9 in the placebo group. Which of the following represents the relative risk reduction for severe cutaneous reactions among patients in the new drug group?

○ A. 0.08
○ B. 0.10
○ C. 0.12
○ D. 0.33
○ E. 0.67

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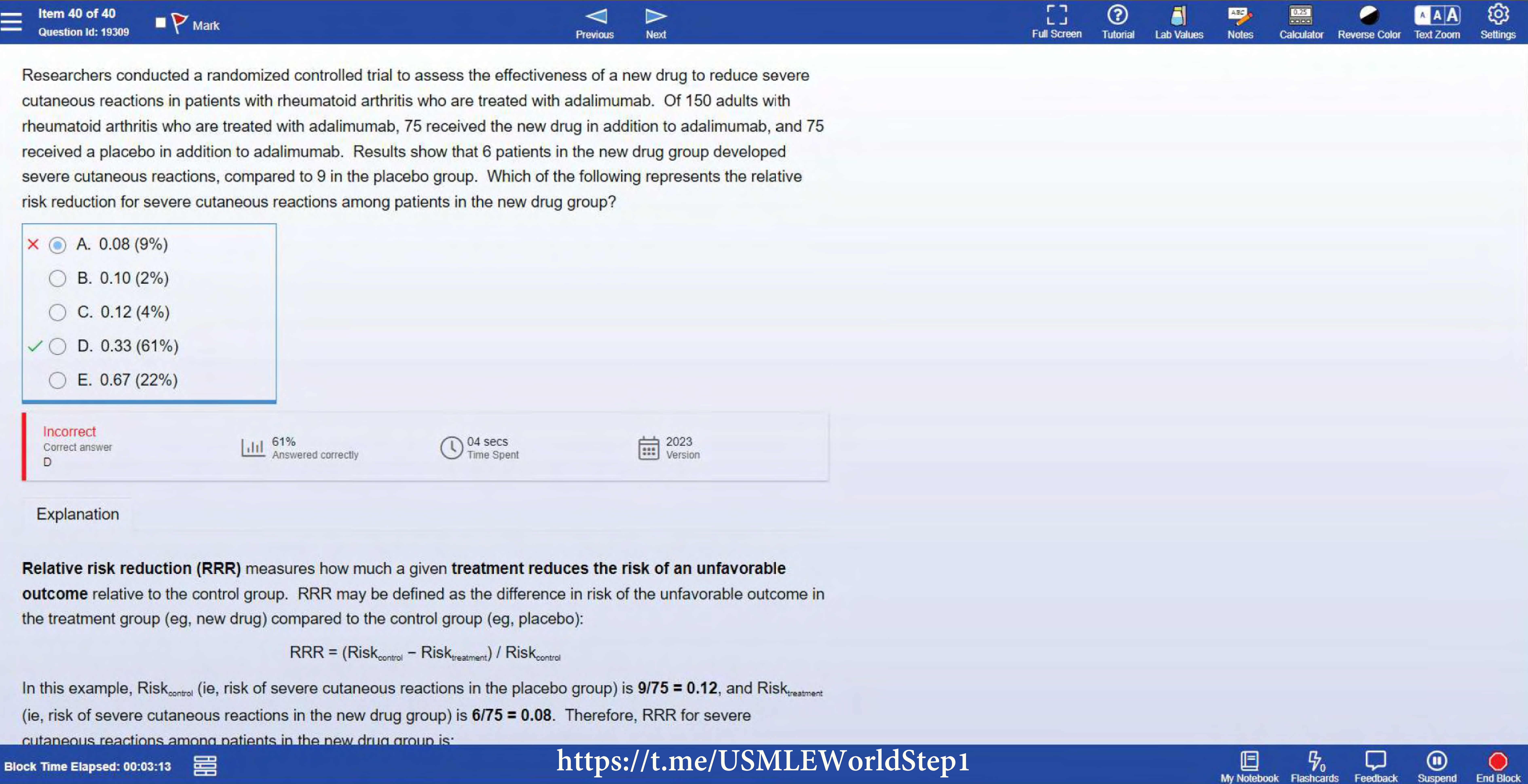
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- ✗ ● A. 0.08 (9%)
- ○ B. 0.10 (2%)
- ○ C. 0.12 (4%)
- ✓ ○ D. 0.33 (61%)
- ○ E. 0.67 (22%)

Incorrect
Correct answer
D

61%
Answered correctly

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Version

Explanation

Relative risk reduction (RRR) measures how much a given **treatment reduces the risk of an unfavorable outcome** relative to the control group. RRR may be defined as the difference in risk of the unfavorable outcome in the treatment group (eg, new drug) compared to the control group (eg, placebo):

$$RRR = (Risk_{control} - Risk_{treatment}) / Risk_{control}$$

In this example, $Risk_{control}$ (ie, risk of severe cutaneous reactions in the placebo group) is **9/75 = 0.12**, and $Risk_{treatment}$ (ie, risk of severe cutaneous reactions in the new drug group) is **6/75 = 0.08**. Therefore, RRR for severe cutaneous reactions among patients in the new drug group is:

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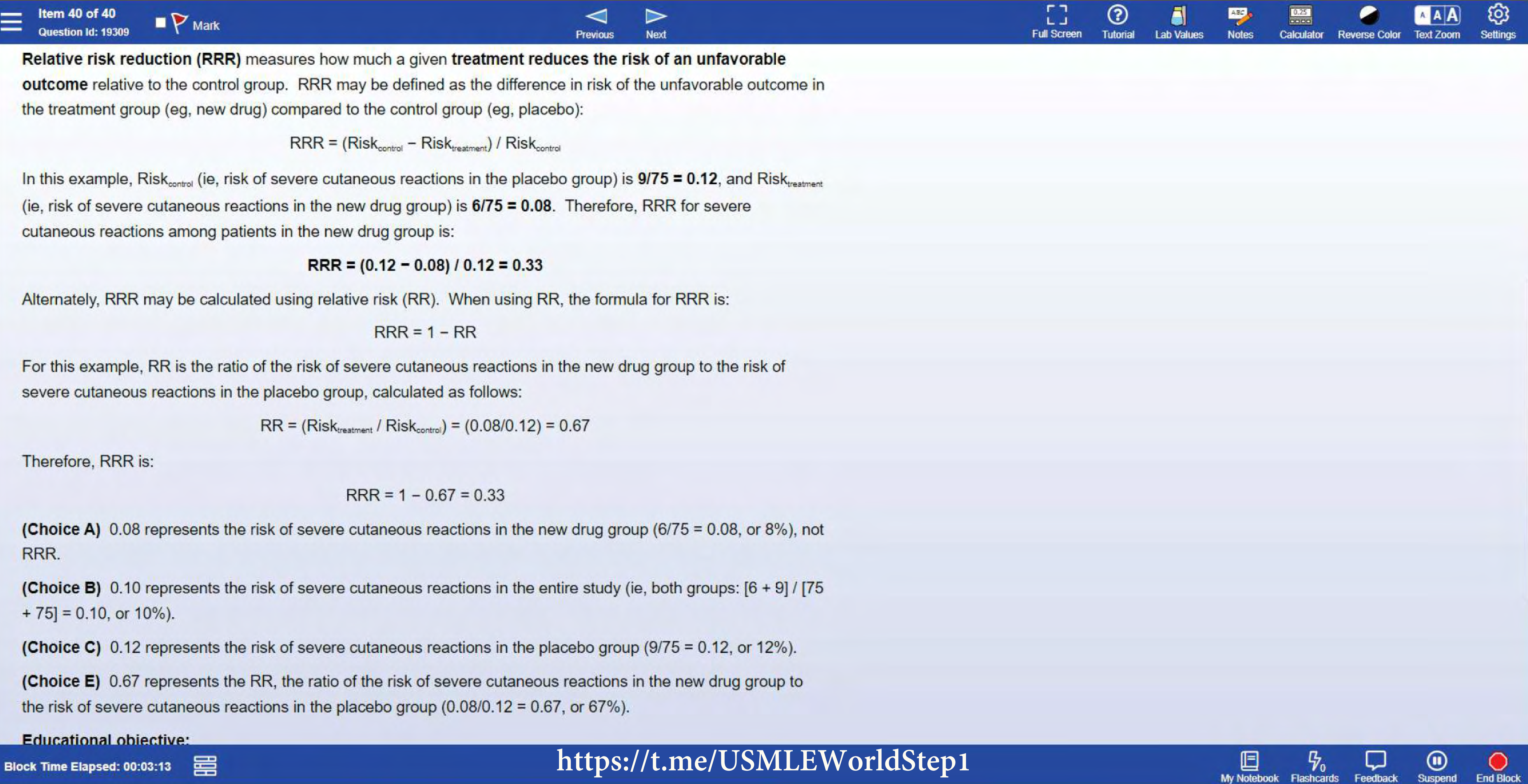

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Relative risk reduction (RRR) measures how much a given **treatment reduces the risk of an unfavorable outcome** relative to the control group. RRR may be defined as the difference in risk of the unfavorable outcome in the treatment group (eg, new drug) compared to the control group (eg, placebo):

$$RRR = (Risk_{control} - Risk_{treatment}) / Risk_{control}$$

In this example, $Risk_{control}$ (ie, risk of severe cutaneous reactions in the placebo group) is **9/75 = 0.12**, and $Risk_{treatment}$ (ie, risk of severe cutaneous reactions in the new drug group) is **6/75 = 0.08**. Therefore, RRR for severe cutaneous reactions among patients in the new drug group is:

$$\mathbf{RRR = (0.12 - 0.08) / 0.12 = 0.33}$$

Alternately, RRR may be calculated using relative risk (RR). When using RR, the formula for RRR is:

$$RRR = 1 - RR$$

For this example, RR is the ratio of the risk of severe cutaneous reactions in the new drug group to the risk of severe cutaneous reactions in the placebo group, calculated as follows:

$$RR = (Risk_{treatment} / Risk_{control}) = (0.08/0.12) = 0.67$$

Therefore, RRR is:

$$RRR = 1 - 0.67 = 0.33$$

(Choice A) 0.08 represents the risk of severe cutaneous reactions in the new drug group (6/75 = 0.08, or 8%), not RRR.

(Choice B) 0.10 represents the risk of severe cutaneous reactions in the entire study (ie, both groups: [6 + 9] / [75 + 75] = 0.10, or 10%).

(Choice C) 0.12 represents the risk of severe cutaneous reactions in the placebo group (9/75 = 0.12, or 12%).

(Choice E) 0.67 represents the RR, the ratio of the risk of severe cutaneous reactions in the new drug group to the risk of severe cutaneous reactions in the placebo group (0.08/0.12 = 0.67, or 67%).

Educational objective:

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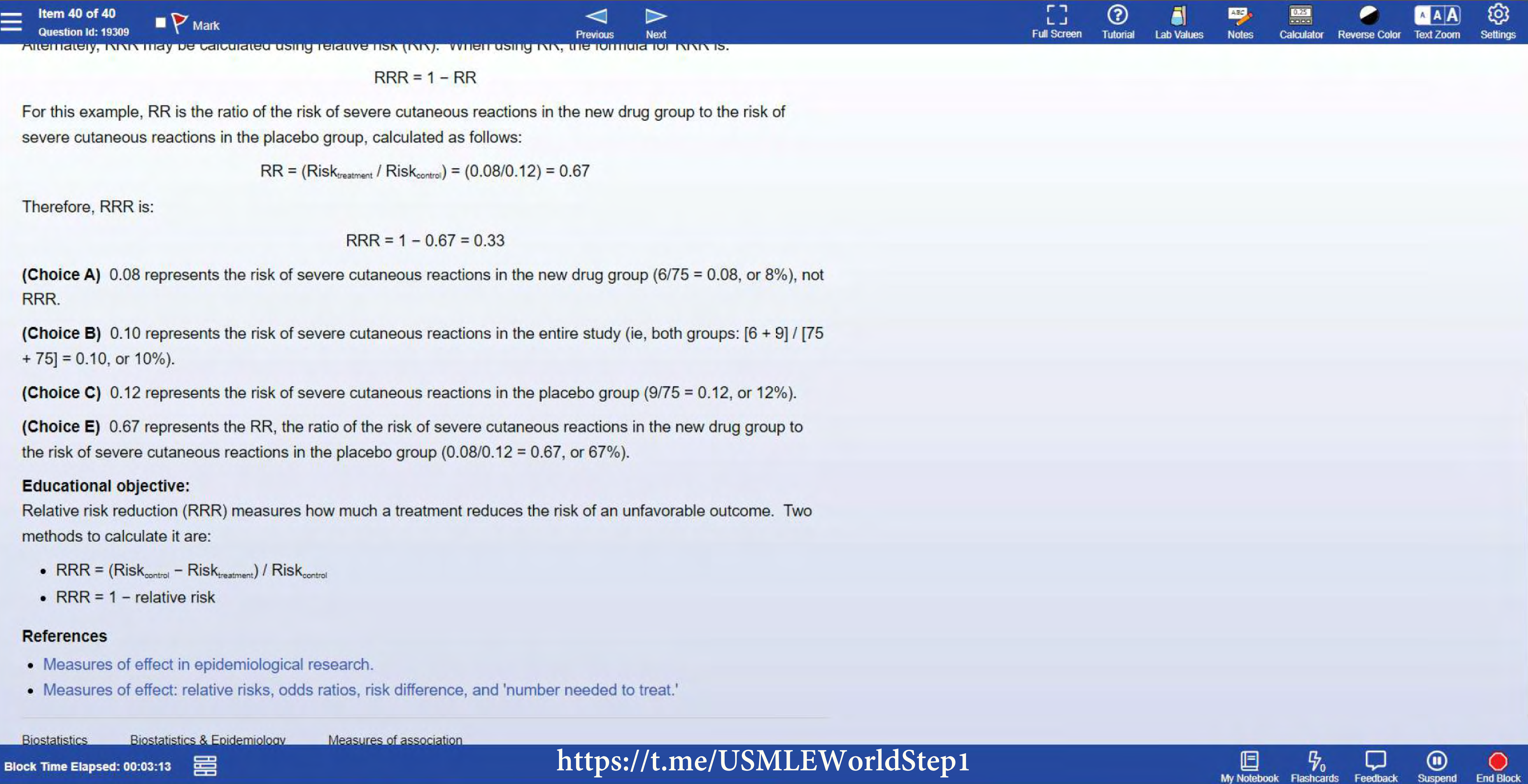
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Alternately, RRR may be calculated using relative risk (RR). When using RR, the formula for RRR is:

$$RRR = 1 - RR$$

For this example, RR is the ratio of the risk of severe cutaneous reactions in the new drug group to the risk of severe cutaneous reactions in the placebo group, calculated as follows:

$$RR = (Risk_{treatment} / Risk_{control}) = (0.08/0.12) = 0.67$$

Therefore, RRR is:

$$RRR = 1 - 0.67 = 0.33$$

(Choice A) 0.08 represents the risk of severe cutaneous reactions in the new drug group (6/75 = 0.08, or 8%), not RRR.

(Choice B) 0.10 represents the risk of severe cutaneous reactions in the entire study (ie, both groups: [6 + 9] / [75 + 75] = 0.10, or 10%).

(Choice C) 0.12 represents the risk of severe cutaneous reactions in the placebo group (9/75 = 0.12, or 12%).

(Choice E) 0.67 represents the RR, the ratio of the risk of severe cutaneous reactions in the new drug group to the risk of severe cutaneous reactions in the placebo group (0.08/0.12 = 0.67, or 67%).

Educational objective:
Relative risk reduction (RRR) measures how much a treatment reduces the risk of an unfavorable outcome. Two methods to calculate it are:

- $RRR = (Risk_{control} - Risk_{treatment}) / Risk_{control}$
- RRR = 1 − relative risk

References

- Measures of effect in epidemiological research.
- Measures of effect: relative risks, odds ratios, risk difference, and 'number needed to treat.'

Biostatistics Biostatistics & Epidemiology Measures of association

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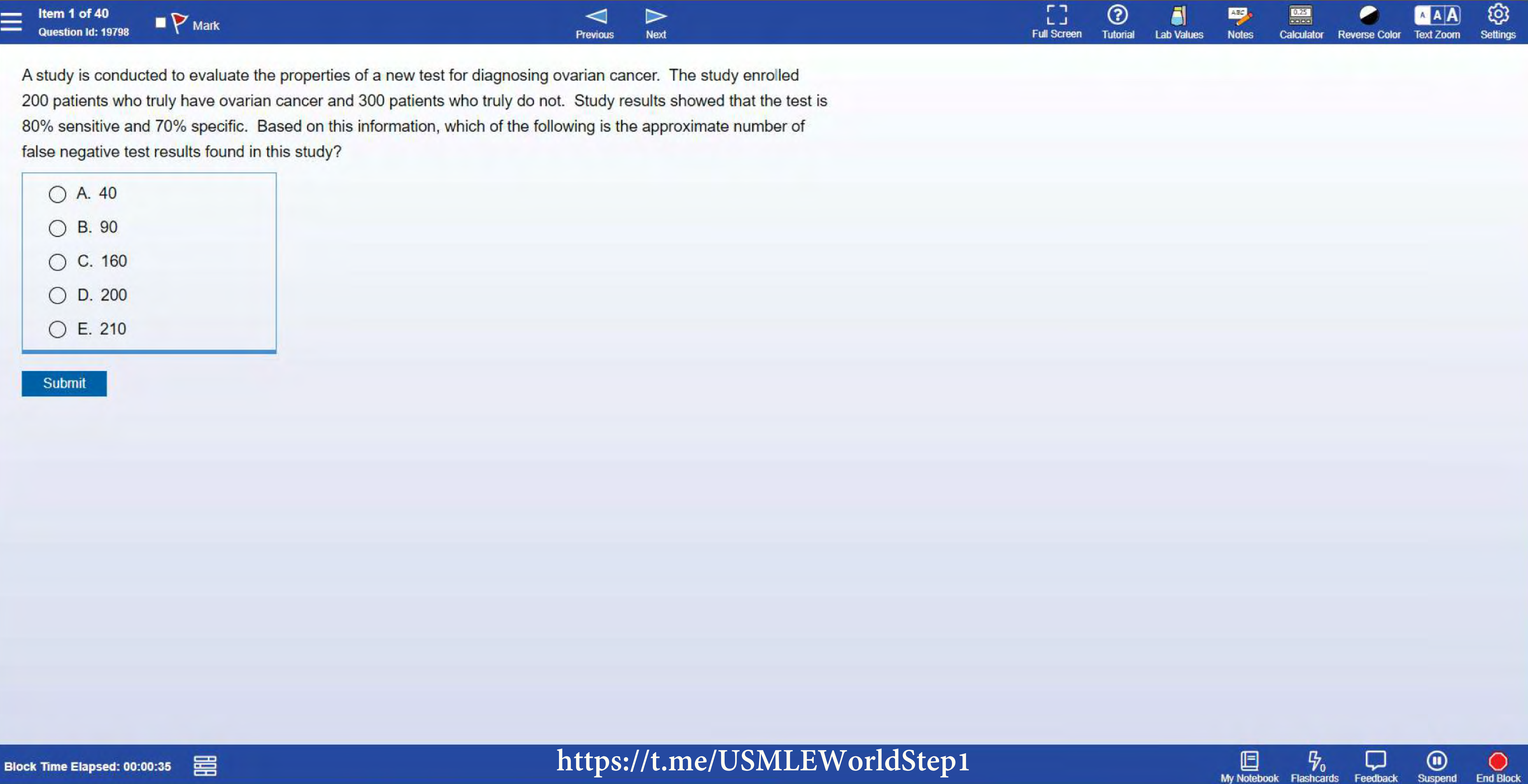
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A study is conducted to evaluate the properties of a new test for diagnosing ovarian cancer. The study enrolled 200 patients who truly have ovarian cancer and 300 patients who truly do not. Study results showed that the test is 80% sensitive and 70% specific. Based on this information, which of the following is the approximate number of false negative test results found in this study?

○ A. 40
○ B. 90
○ C. 160
○ D. 200
○ E. 210

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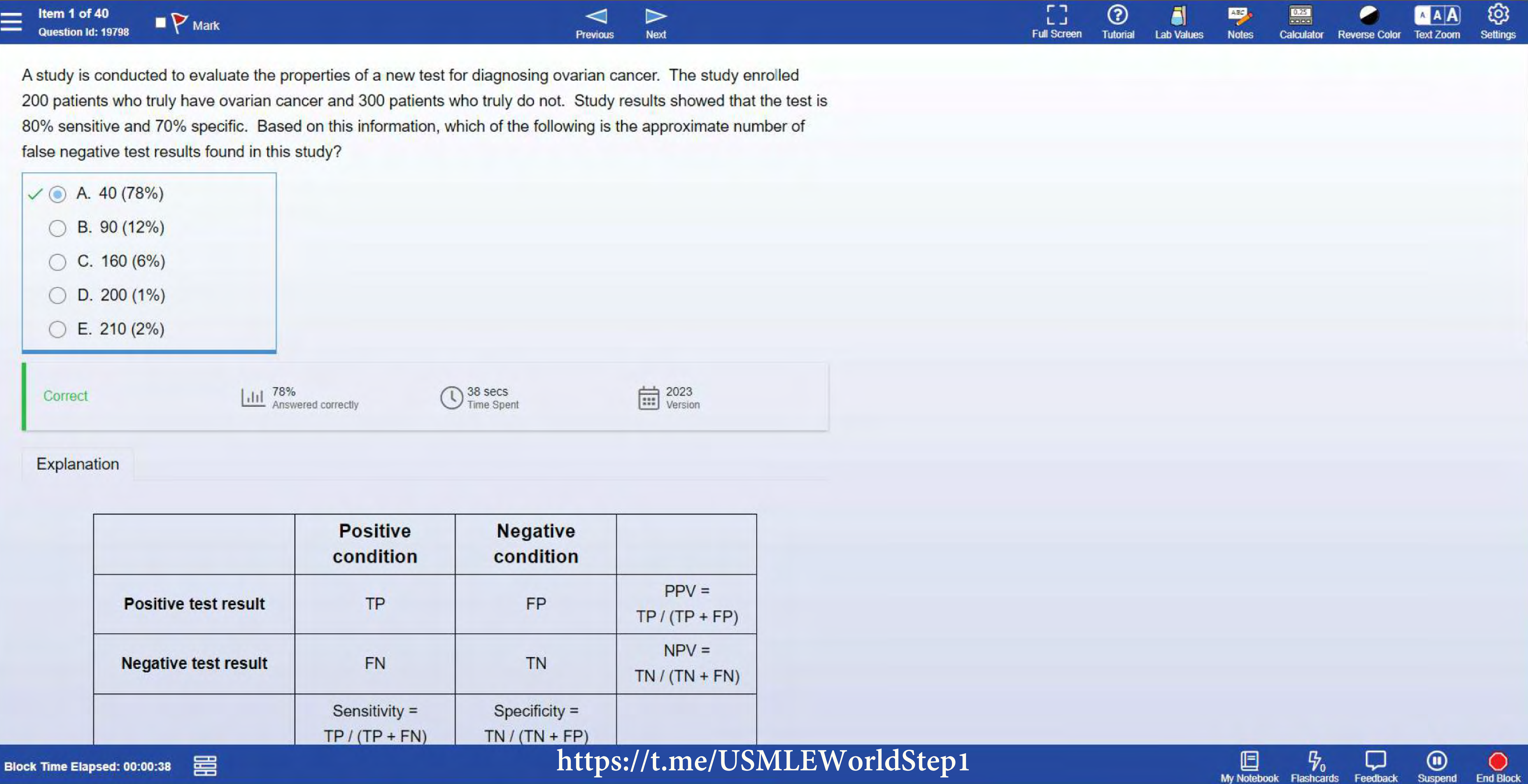
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A study is conducted to evaluate the properties of a new test for diagnosing ovarian cancer. The study enrolled 200 patients who truly have ovarian cancer and 300 patients who truly do not. Study results showed that the test is 80% sensitive and 70% specific. Based on this information, which of the following is the approximate number of false negative test results found in this study?

✓ ● A. 40 (78%)
○ B. 90 (12%)
○ C. 160 (6%)
○ D. 200 (1%)
○ E. 210 (2%)

Correct

78% Answered correctly

38 secs Time Spent

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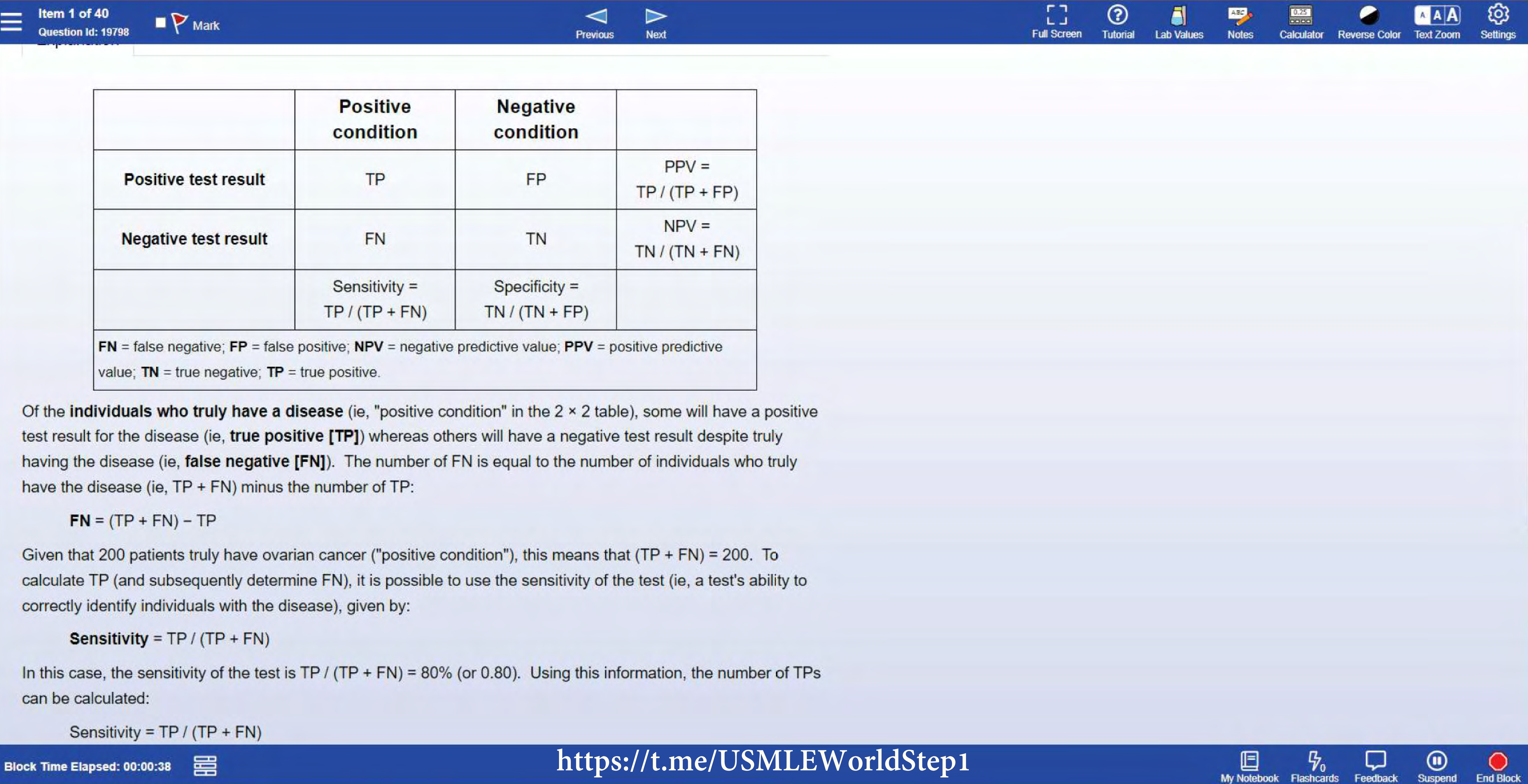
Explanation

	Positive condition	**Negative condition**	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	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	Positive condition	**Negative condition**	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

Of the **individuals who truly have a disease** (ie, "positive condition" in the 2 × 2 table), some will have a positive test result for the disease (ie, **true positive [TP]**) whereas others will have a negative test result despite truly having the disease (ie, **false negative [FN]**). The number of FN is equal to the number of individuals who truly have the disease (ie, TP + FN) minus the number of TP:

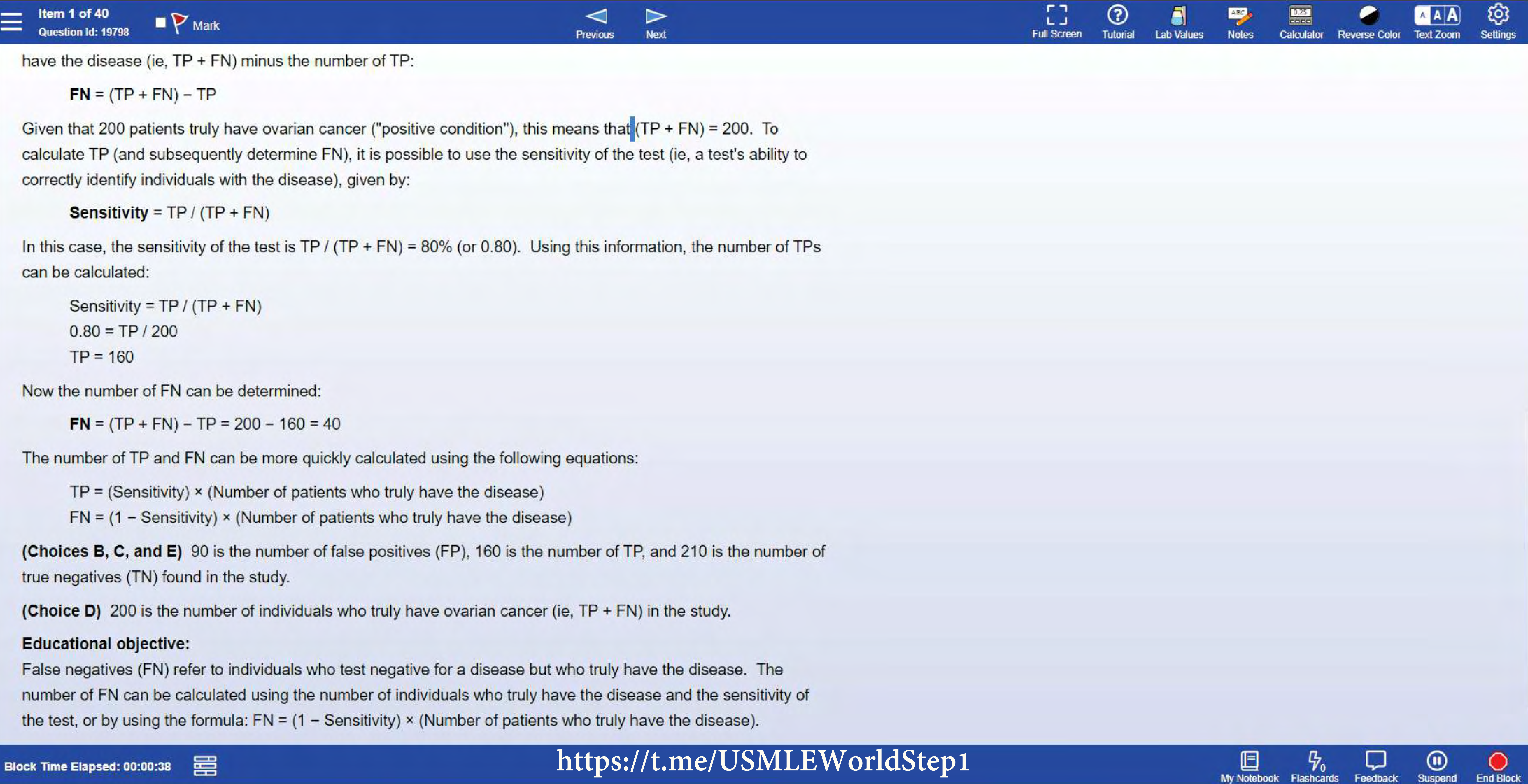
FN = (TP + FN) – TP

Given that 200 patients truly have ovarian cancer ("positive condition"), this means that (TP + FN) = 200. To calculate TP (and subsequently determine FN), it is possible to use the sensitivity of the test (ie, a test's ability to correctly identify individuals with the disease), given by:

Sensitivity = TP / (TP + FN)

In this case, the sensitivity of the test is TP / (TP + FN) = 80% (or 0.80). Using this information, the number of TPs can be calculated:

Sensitivity = TP / (TP + FN)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have the disease (ie, TP + FN) minus the number of TP:

FN = (TP + FN) − TP

Given that 200 patients truly have ovarian cancer ("positive condition"), this means that (TP + FN) = 200. To calculate TP (and subsequently determine FN), it is possible to use the sensitivity of the test (ie, a test's ability to correctly identify individuals with the disease), given by:

Sensitivity = TP / (TP + FN)

In this case, the sensitivity of the test is TP / (TP + FN) = 80% (or 0.80). Using this information, the number of TPs can be calculated:

Sensitivity = TP / (TP + FN)
0.80 = TP / 200
TP = 160

Now the number of FN can be determined:

FN = (TP + FN) − TP = 200 − 160 = 40

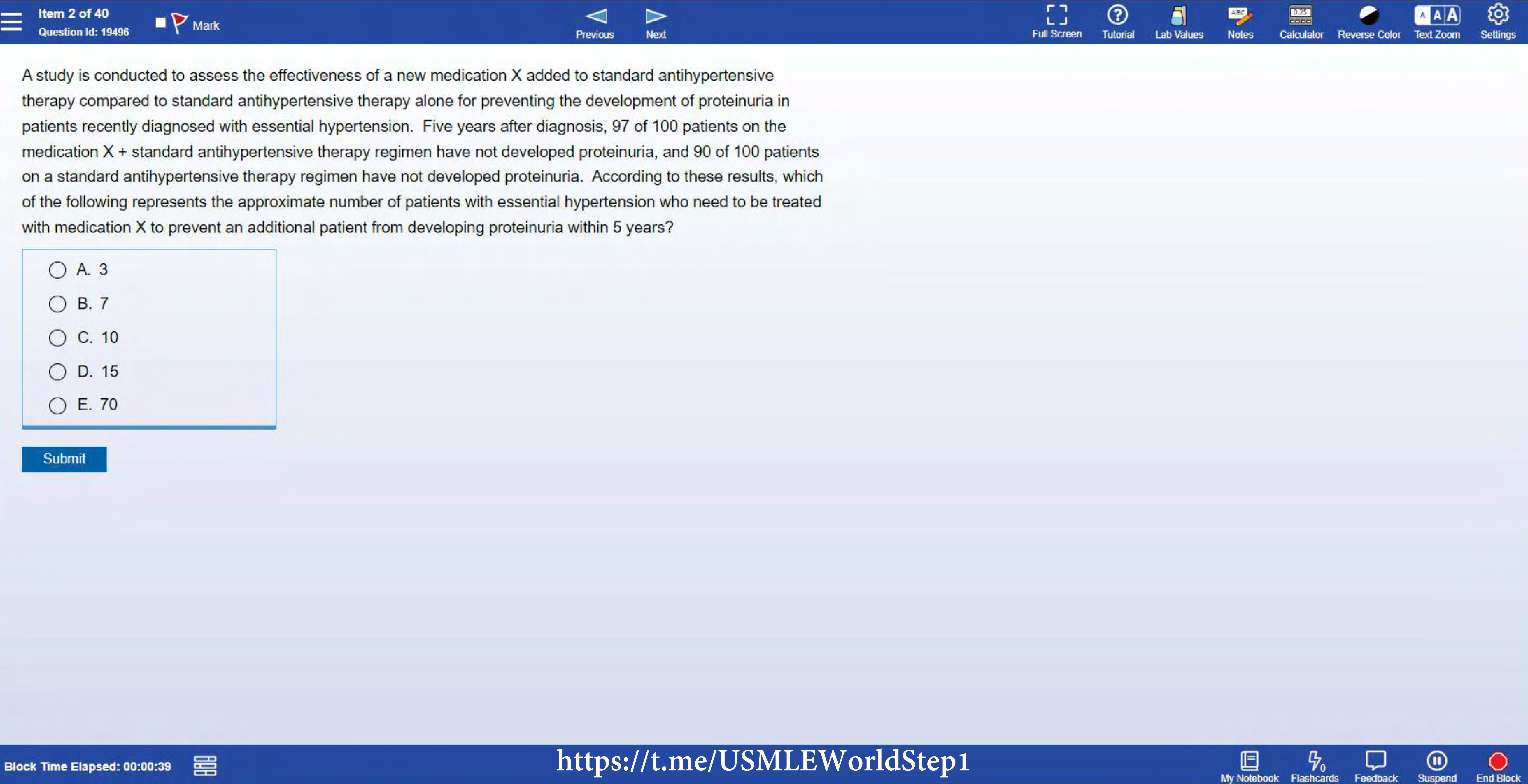
The number of TP and FN can be more quickly calculated using the following equations:

TP = (Sensitivity) × (Number of patients who truly have the disease)
FN = (1 − Sensitivity) × (Number of patients who truly have the disease)

(Choices B, C, and E) 90 is the number of false positives (FP), 160 is the number of TP, and 210 is the number of true negatives (TN) found in the study.

(Choice D) 200 is the number of individuals who truly have ovarian cancer (ie, TP + FN) in the study.

Educational objective:
False negatives (FN) refer to individuals who test negative for a disease but who truly have the disease. The number of FN can be calculated using the number of individuals who truly have the disease and the sensitivity of the test, or by using the formula: FN = (1 − Sensitivity) × (Number of patients who truly have the disease).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A study is conducted to assess the effectiveness of a new medication X added to standard antihypertensive therapy compared to standard antihypertensive therapy alone for preventing the development of proteinuria in patients recently diagnosed with essential hypertension. Five years after diagnosis, 97 of 100 patients on the medication X + standard antihypertensive therapy regimen have not developed proteinuria, and 90 of 100 patients on a standard antihypertensive therapy regimen have not developed proteinuria. According to these results, which of the following represents the approximate number of patients with essential hypertension who need to be treated with medication X to prevent an additional patient from developing proteinuria within 5 years?

○ A. 3
○ B. 7
○ C. 10
○ D. 15
○ E. 70

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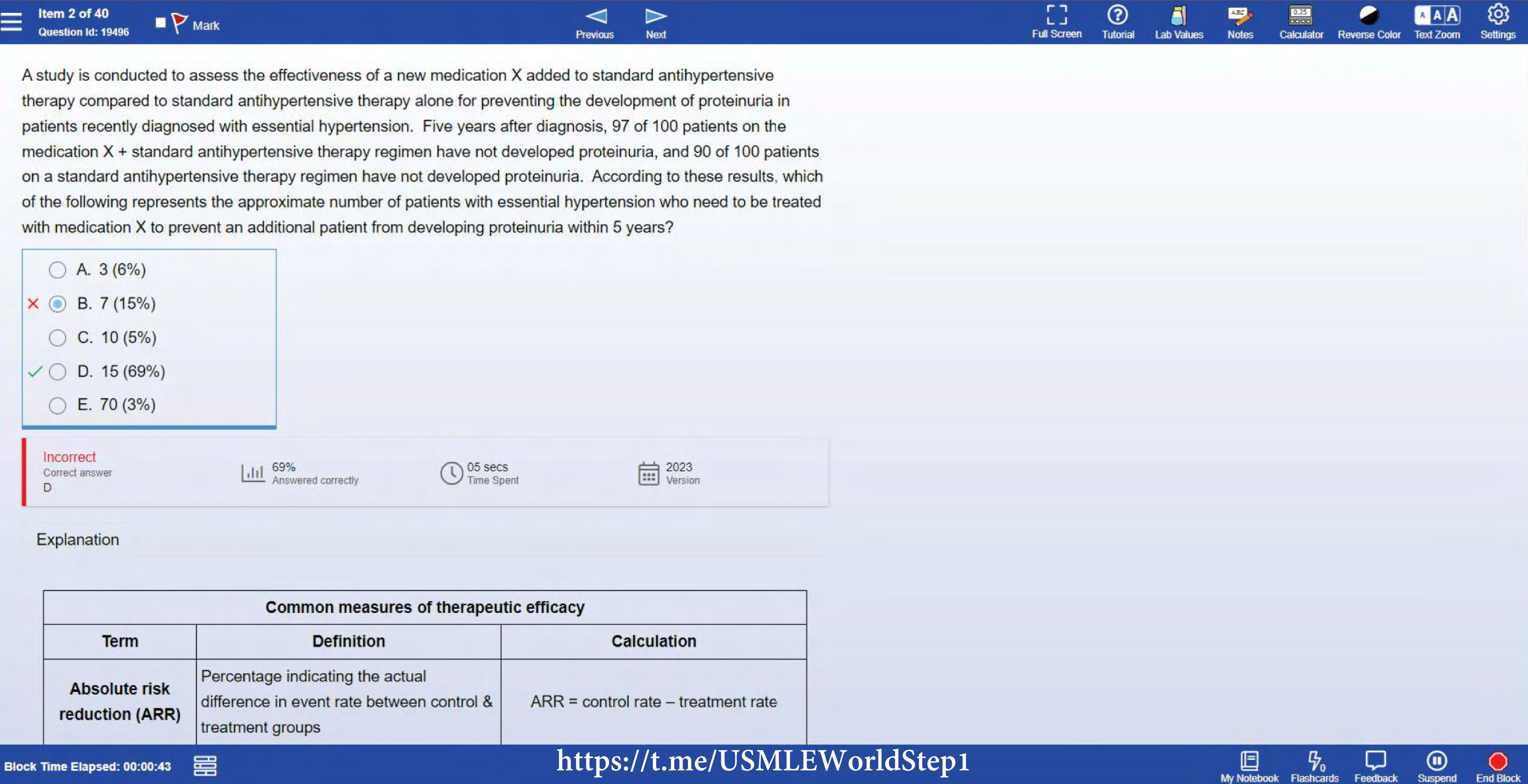
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- ○ A. 3 (6%)
- ✗ ● B. 7 (15%)
- ○ C. 10 (5%)
- ✓ ○ D. 15 (69%)
- ○ E. 70 (3%)

Incorrect
Correct answer
D

69%
Answered correctly

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Explanation

Common measures of therapeutic efficacy		
Term	**Definition**	**Calculation**
Absolute risk reduction (ARR)	Percentage indicating the actual difference in event rate between control & treatment groups	ARR = control rate – treatment rate

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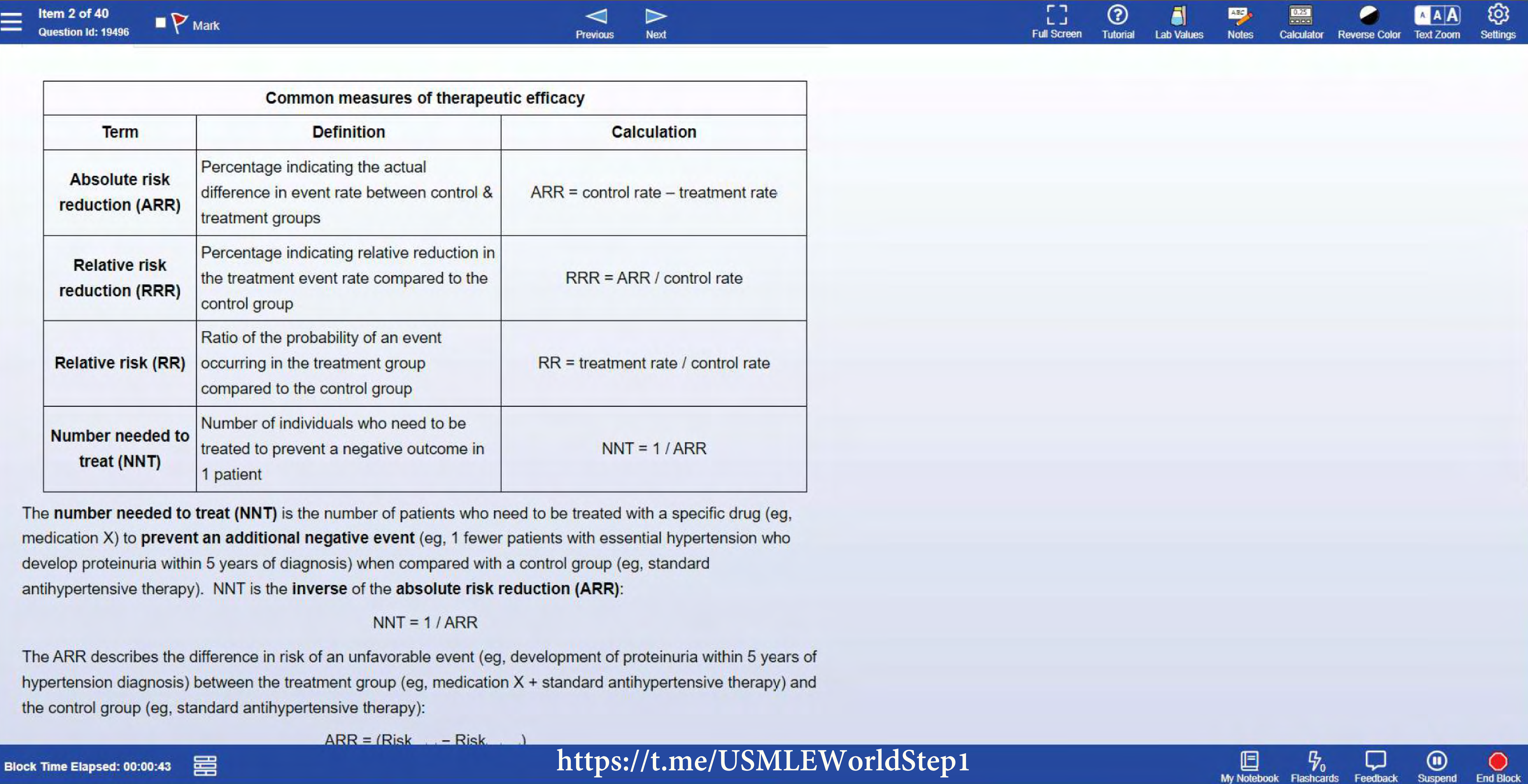
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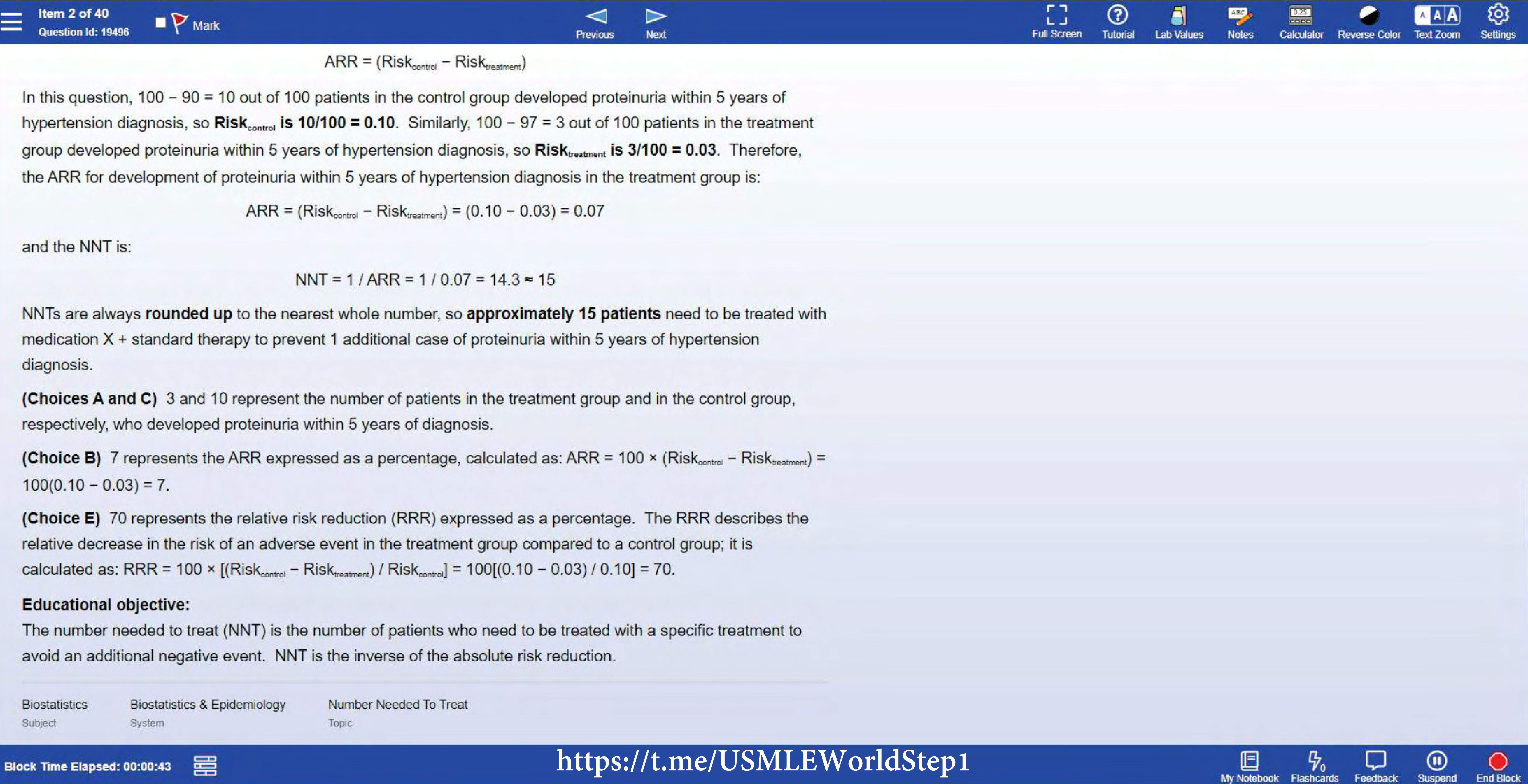
Common measures of therapeutic efficacy		
Term	**Definition**	**Calculation**
Absolute risk reduction (ARR)	Percentage indicating the actual difference in event rate between control & treatment groups	ARR = control rate – treatment rate
Relative risk reduction (RRR)	Percentage indicating relative reduction in the treatment event rate compared to the control group	RRR = ARR / control rate
Relative risk (RR)	Ratio of the probability of an event occurring in the treatment group compared to the control group	RR = treatment rate / control rate
Number needed to treat (NNT)	Number of individuals who need to be treated to prevent a negative outcome in 1 patient	NNT = 1 / ARR

The **number needed to treat (NNT)** is the number of patients who need to be treated with a specific drug (eg, medication X) to **prevent an additional negative event** (eg, 1 fewer patients with essential hypertension who develop proteinuria within 5 years of diagnosis) when compared with a control group (eg, standard antihypertensive therapy). NNT is the **inverse** of the **absolute risk reduction (ARR)**:

$$NNT = 1 / ARR$$

The ARR describes the difference in risk of an unfavorable event (eg, development of proteinuria within 5 years of hypertension diagnosis) between the treatment group (eg, medication X + standard antihypertensive therapy) and the control group (eg, standard antihypertensive therapy):

ARR = (Risk − Risk)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$$ARR = (Risk_{control} - Risk_{treatment})$$

In this question, 100 − 90 = 10 out of 100 patients in the control group developed proteinuria within 5 years of hypertension diagnosis, so **$Risk_{control}$ is 10/100 = 0.10**. Similarly, 100 − 97 = 3 out of 100 patients in the treatment group developed proteinuria within 5 years of hypertension diagnosis, so **$Risk_{treatment}$ is 3/100 = 0.03**. Therefore, the ARR for development of proteinuria within 5 years of hypertension diagnosis in the treatment group is:

$$ARR = (Risk_{control} - Risk_{treatment}) = (0.10 - 0.03) = 0.07$$

and the NNT is:

$$NNT = 1 / ARR = 1 / 0.07 = 14.3 \approx 15$$

NNTs are always **rounded up** to the nearest whole number, so **approximately 15 patients** need to be treated with medication X + standard therapy to prevent 1 additional case of proteinuria within 5 years of hypertension diagnosis.

(Choices A and C) 3 and 10 represent the number of patients in the treatment group and in the control group, respectively, who developed proteinuria within 5 years of diagnosis.

(Choice B) 7 represents the ARR expressed as a percentage, calculated as: $ARR = 100 \times (Risk_{control} - Risk_{treatment}) = 100(0.10 - 0.03) = 7$.

(Choice E) 70 represents the relative risk reduction (RRR) expressed as a percentage. The RRR describes the relative decrease in the risk of an adverse event in the treatment group compared to a control group; it is calculated as: $RRR = 100 \times [(Risk_{control} - Risk_{treatment}) / Risk_{control}] = 100[(0.10 - 0.03) / 0.10] = 70$.

Educational objective:

The number needed to treat (NNT) is the number of patients who need to be treated with a specific treatment to avoid an additional negative event. NNT is the inverse of the absolute risk reduction.

Biostatistics	Biostatistics & Epidemiology	Number Needed To Treat
Subject	System	Topic

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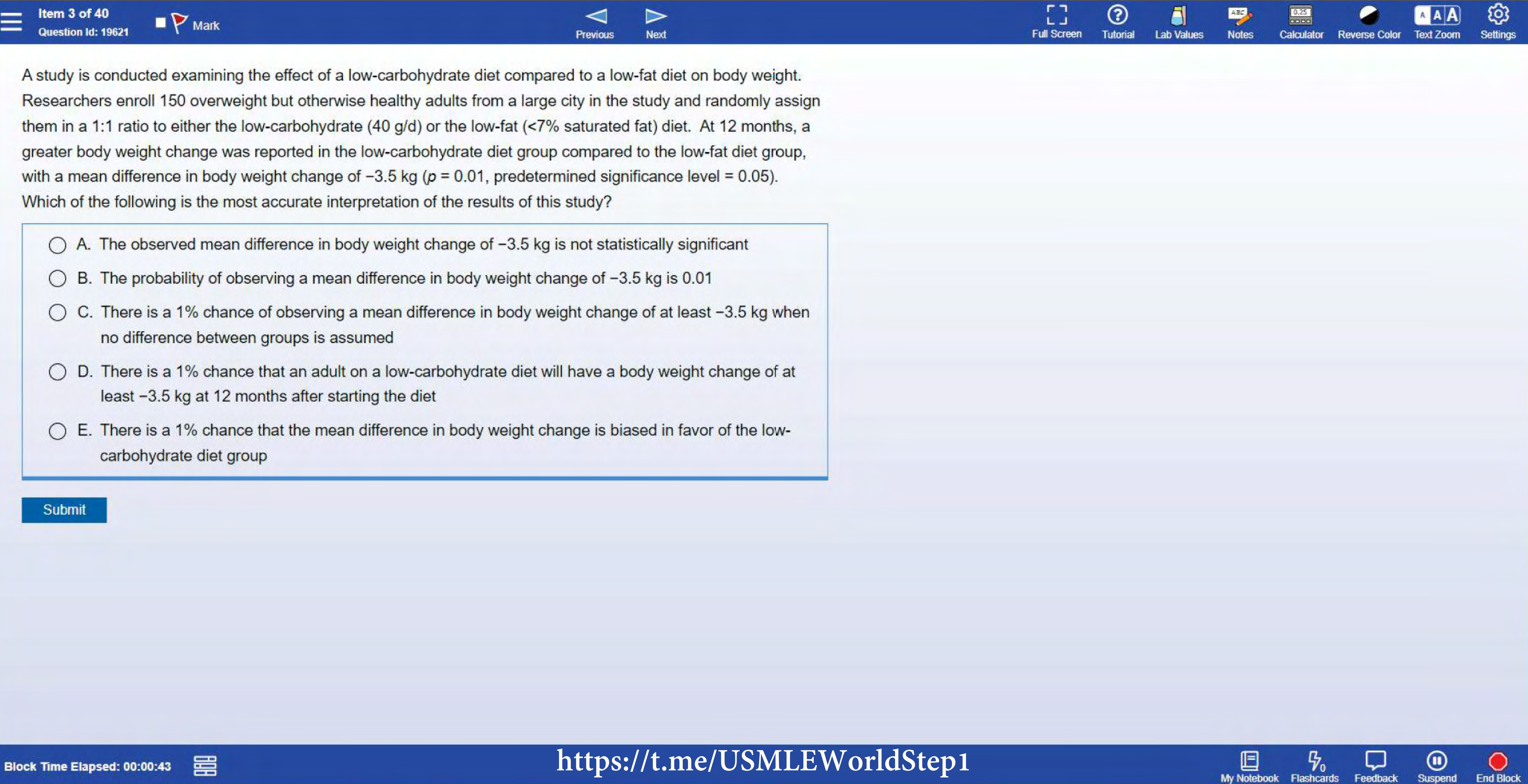
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A study is conducted examining the effect of a low-carbohydrate diet compared to a low-fat diet on body weight. Researchers enroll 150 overweight but otherwise healthy adults from a large city in the study and randomly assign them in a 1:1 ratio to either the low-carbohydrate (40 g/d) or the low-fat (<7% saturated fat) diet. At 12 months, a greater body weight change was reported in the low-carbohydrate diet group compared to the low-fat diet group, with a mean difference in body weight change of −3.5 kg ($p = 0.01$, predetermined significance level = 0.05). Which of the following is the most accurate interpretation of the results of this study?

- ○ A. The observed mean difference in body weight change of −3.5 kg is not statistically significant
- ○ B. The probability of observing a mean difference in body weight change of −3.5 kg is 0.01
- ○ C. There is a 1% chance of observing a mean difference in body weight change of at least −3.5 kg when no difference between groups is assumed
- ○ D. There is a 1% chance that an adult on a low-carbohydrate diet will have a body weight change of at least −3.5 kg at 12 months after starting the diet
- ○ E. There is a 1% chance that the mean difference in body weight change is biased in favor of the low-carbohydrate diet group

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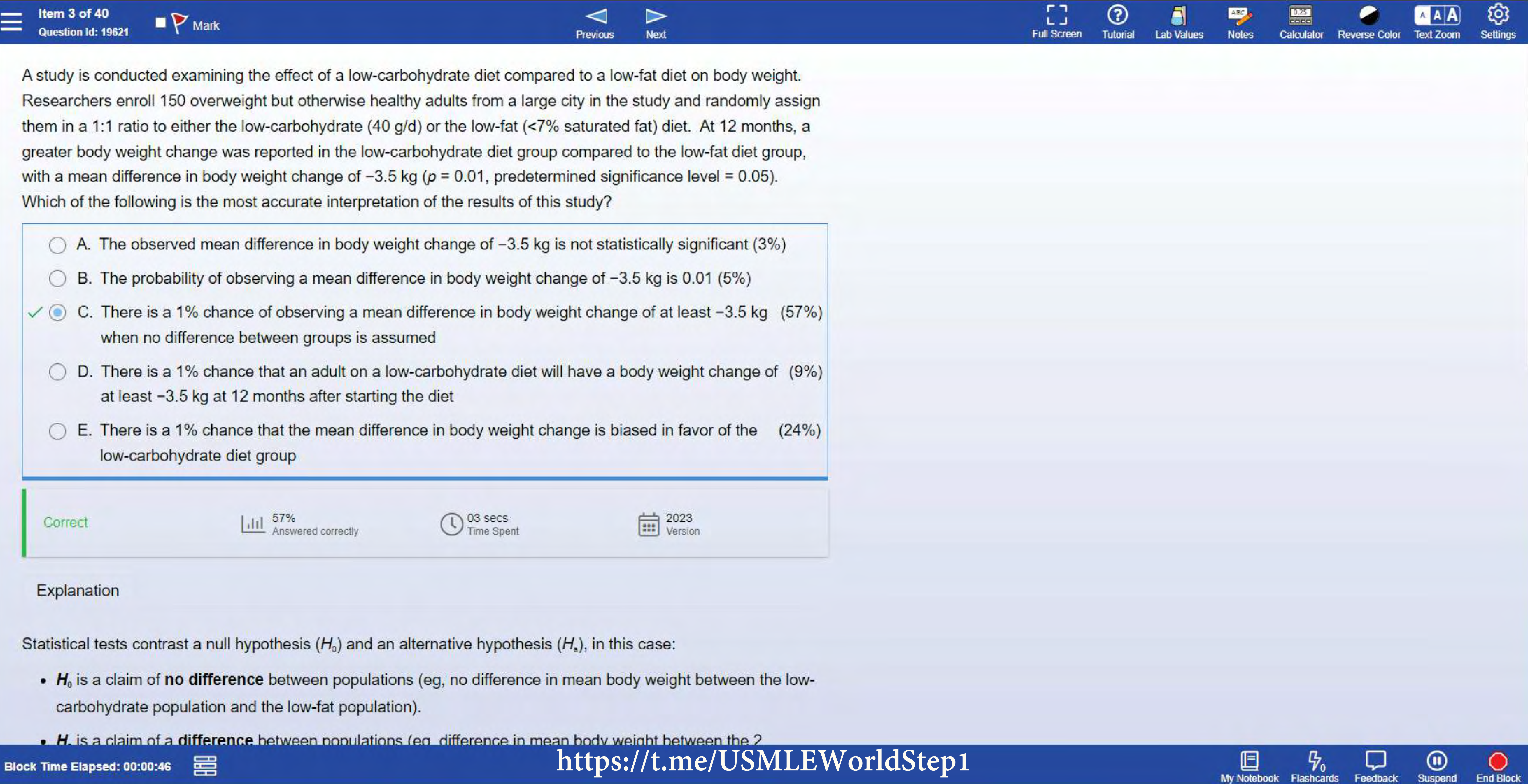
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- ○ A. The observed mean difference in body weight change of −3.5 kg is not statistically significant (3%)
- ○ B. The probability of observing a mean difference in body weight change of −3.5 kg is 0.01 (5%)
- ✓ ● C. There is a 1% chance of observing a mean difference in body weight change of at least −3.5 kg when no difference between groups is assumed (57%)
- ○ D. There is a 1% chance that an adult on a low-carbohydrate diet will have a body weight change of at least −3.5 kg at 12 months after starting the diet (9%)
- ○ E. There is a 1% chance that the mean difference in body weight change is biased in favor of the low-carbohydrate diet group (24%)

Correct

57%
Answered correctly

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Explanation

Statistical tests contrast a null hypothesis (H_0) and an alternative hypothesis (H_a), in this case:

- ***H_0*** is a claim of **no difference** between populations (eg, no difference in mean body weight between the low-carbohydrate population and the low-fat population).
- ***H_a*** is a claim of a **difference** between populations (eg, difference in mean body weight between the 2

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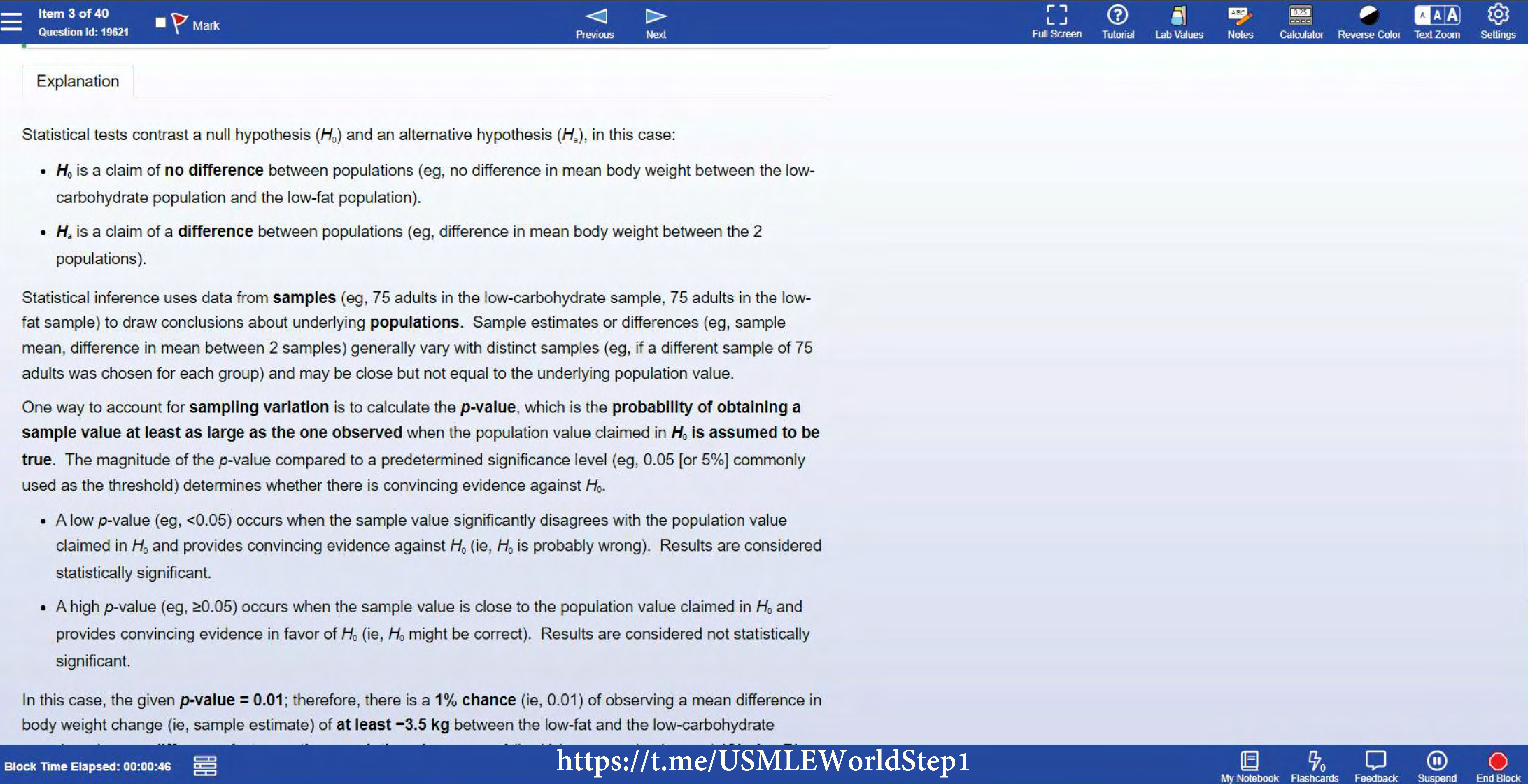
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Statistical tests contrast a null hypothesis (H_0) and an alternative hypothesis (H_a), in this case:

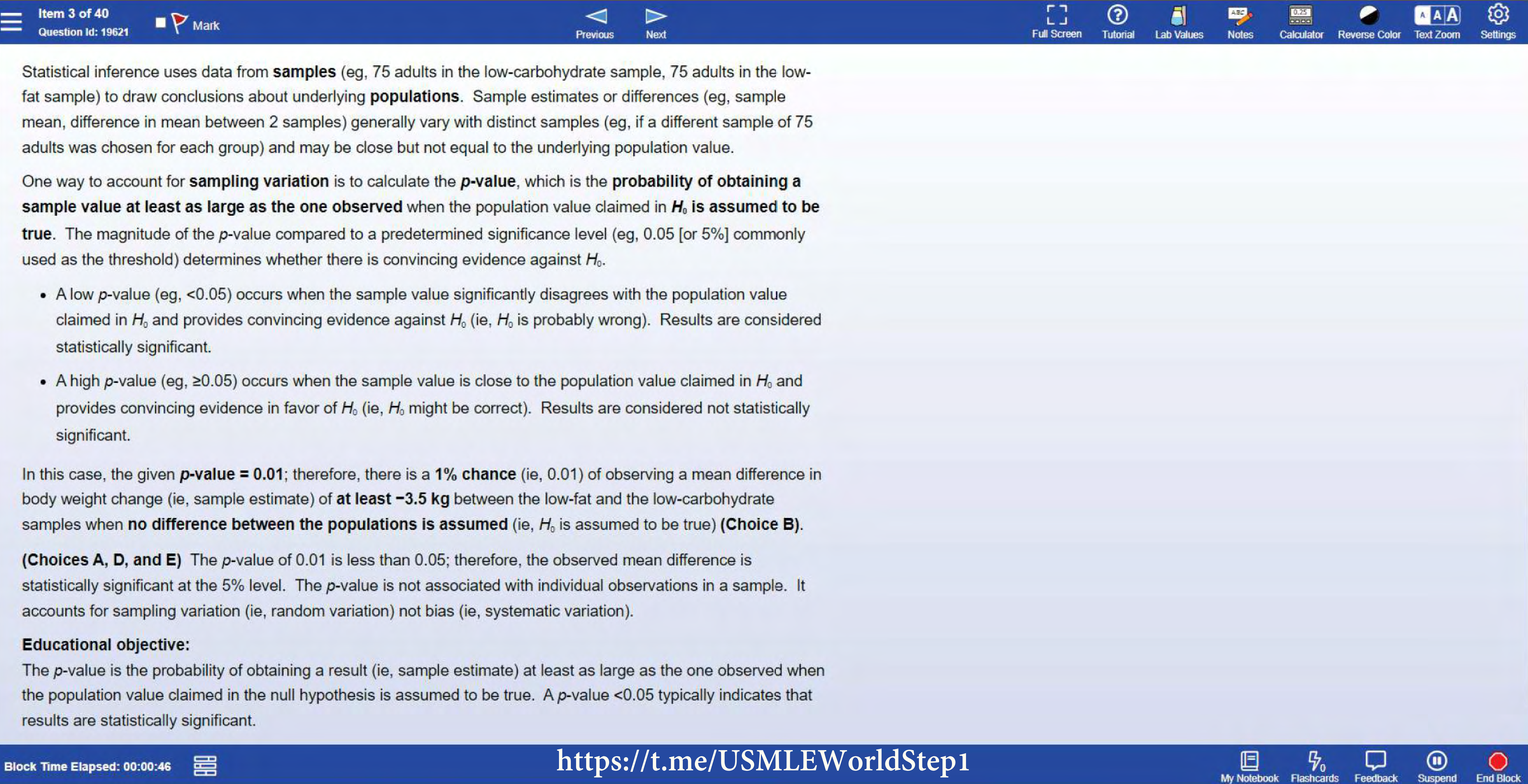
- H_0 is a claim of **no difference** between populations (eg, no difference in mean body weight between the low-carbohydrate population and the low-fat population).
- H_a is a claim of a **difference** between populations (eg, difference in mean body weight between the 2 populations).

Statistical inference uses data from **samples** (eg, 75 adults in the low-carbohydrate sample, 75 adults in the low-fat sample) to draw conclusions about underlying **populations**. Sample estimates or differences (eg, sample mean, difference in mean between 2 samples) generally vary with distinct samples (eg, if a different sample of 75 adults was chosen for each group) and may be close but not equal to the underlying population value.

One way to account for **sampling variation** is to calculate the ***p*-value**, which is the **probability of obtaining a sample value at least as large as the one observed** when the population value claimed in **H_0 is assumed to be true**. The magnitude of the *p*-value compared to a predetermined significance level (eg, 0.05 [or 5%] commonly used as the threshold) determines whether there is convincing evidence against H_0.

- A low *p*-value (eg, <0.05) occurs when the sample value significantly disagrees with the population value claimed in H_0 and provides convincing evidence against H_0 (ie, H_0 is probably wrong). Results are considered statistically significant.
- A high *p*-value (eg, ≥0.05) occurs when the sample value is close to the population value claimed in H_0 and provides convincing evidence in favor of H_0 (ie, H_0 might be correct). Results are considered not statistically significant.

In this case, the given ***p*-value = 0.01**; therefore, there is a **1% chance** (ie, 0.01) of observing a mean difference in body weight change (ie, sample estimate) of **at least −3.5 kg** between the low-fat and the low-carbohydrate



Statistical inference uses data from **samples** (eg, 75 adults in the low-carbohydrate sample, 75 adults in the low-fat sample) to draw conclusions about underlying **populations**. Sample estimates or differences (eg, sample mean, difference in mean between 2 samples) generally vary with distinct samples (eg, if a different sample of 75 adults was chosen for each group) and may be close but not equal to the underlying population value.

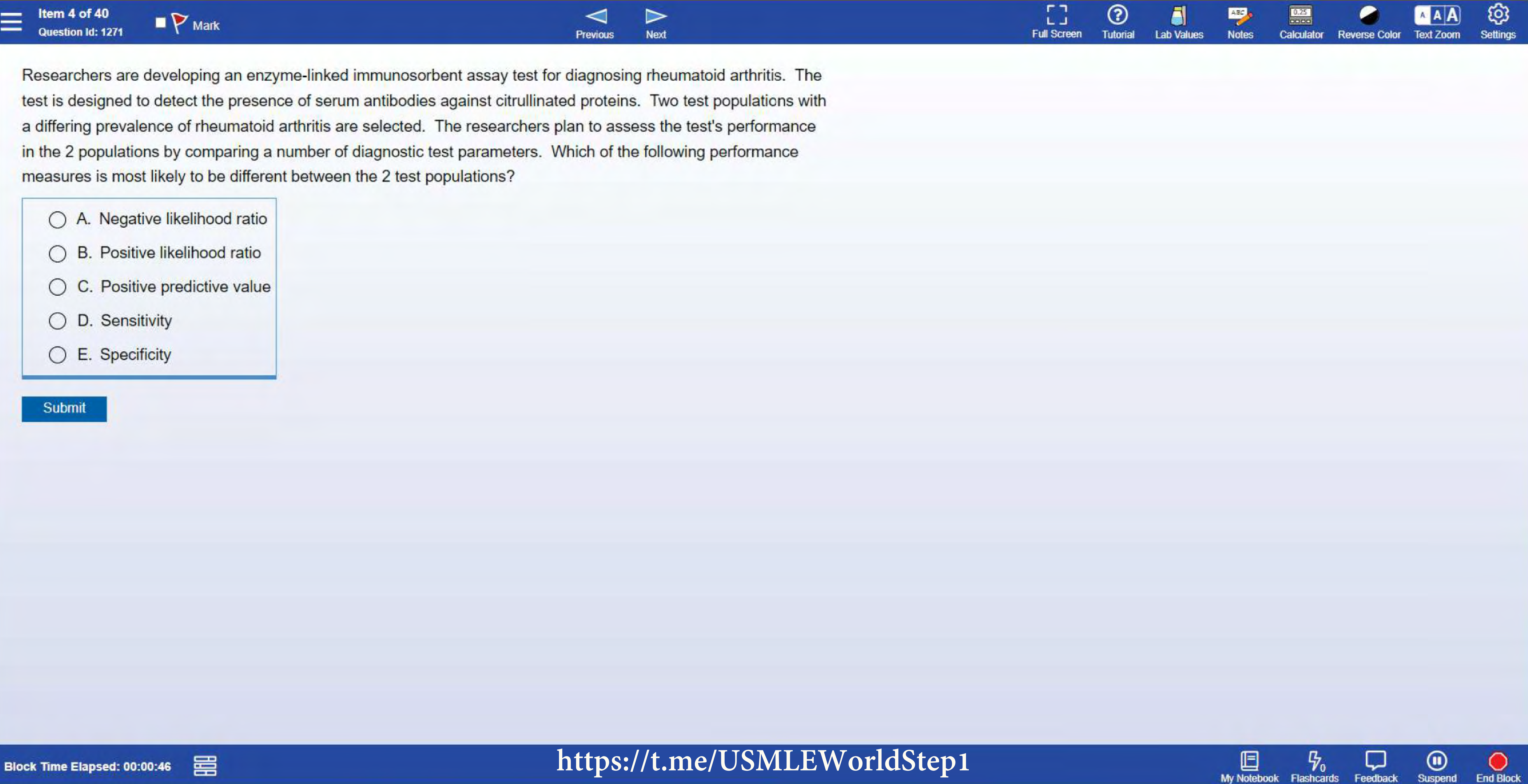
One way to account for **sampling variation** is to calculate the ***p*-value**, which is the **probability of obtaining a sample value at least as large as the one observed** when the population value claimed in **H_0 is assumed to be true**. The magnitude of the *p*-value compared to a predetermined significance level (eg, 0.05 [or 5%] commonly used as the threshold) determines whether there is convincing evidence against H_0.

- A low *p*-value (eg, <0.05) occurs when the sample value significantly disagrees with the population value claimed in H_0 and provides convincing evidence against H_0 (ie, H_0 is probably wrong). Results are considered statistically significant.
- A high *p*-value (eg, ≥ 0.05) occurs when the sample value is close to the population value claimed in H_0 and provides convincing evidence in favor of H_0 (ie, H_0 might be correct). Results are considered not statistically significant.

In this case, the given ***p*-value = 0.01**; therefore, there is a **1% chance** (ie, 0.01) of observing a mean difference in body weight change (ie, sample estimate) of **at least −3.5 kg** between the low-fat and the low-carbohydrate samples when **no difference between the populations is assumed** (ie, H_0 is assumed to be true) **(Choice B)**.

(Choices A, D, and E) The *p*-value of 0.01 is less than 0.05; therefore, the observed mean difference is statistically significant at the 5% level. The *p*-value is not associated with individual observations in a sample. It accounts for sampling variation (ie, random variation) not bias (ie, systematic variation).

Educational objective:
The *p*-value is the probability of obtaining a result (ie, sample estimate) at least as large as the one observed when the population value claimed in the null hypothesis is assumed to be true. A *p*-value <0.05 typically indicates that results are statistically significant.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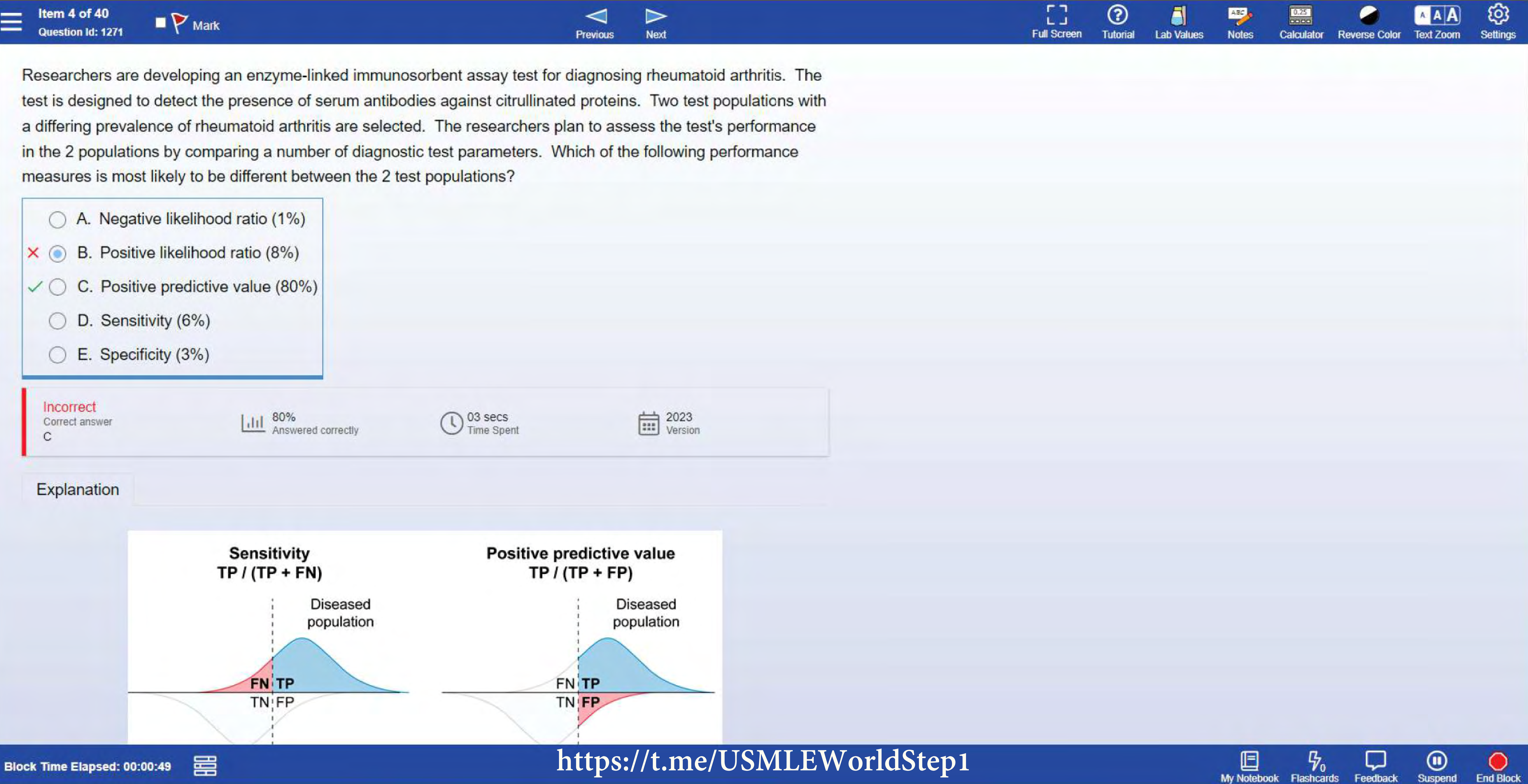
Researchers are developing an enzyme-linked immunosorbent assay test for diagnosing rheumatoid arthritis. The test is designed to detect the presence of serum antibodies against citrullinated proteins. Two test populations with a differing prevalence of rheumatoid arthritis are selected. The researchers plan to assess the test's performance in the 2 populations by comparing a number of diagnostic test parameters. Which of the following performance measures is most likely to be different between the 2 test populations?

○ A. Negative likelihood ratio
○ B. Positive likelihood ratio
○ C. Positive predictive value
○ D. Sensitivity
○ E. Specificity



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Researchers are developing an enzyme-linked immunosorbent assay test for diagnosing rheumatoid arthritis. The test is designed to detect the presence of serum antibodies against citrullinated proteins. Two test populations with a differing prevalence of rheumatoid arthritis are selected. The researchers plan to assess the test's performance in the 2 populations by comparing a number of diagnostic test parameters. Which of the following performance measures is most likely to be different between the 2 test populations?

○ A. Negative likelihood ratio (1%)

✗ ● B. Positive likelihood ratio (8%)

✓ ○ C. Positive predictive value (80%)

○ D. Sensitivity (6%)

○ E. Specificity (3%)

Incorrect
Correct answer
C

80%
Answered correctly

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Explanation

Sensitivity
TP / (TP + FN)

Positive predictive value
TP / (TP + FP)

Diseased population
FN
TP
TN
FP
Diseased population
FN
TP
TN
FP

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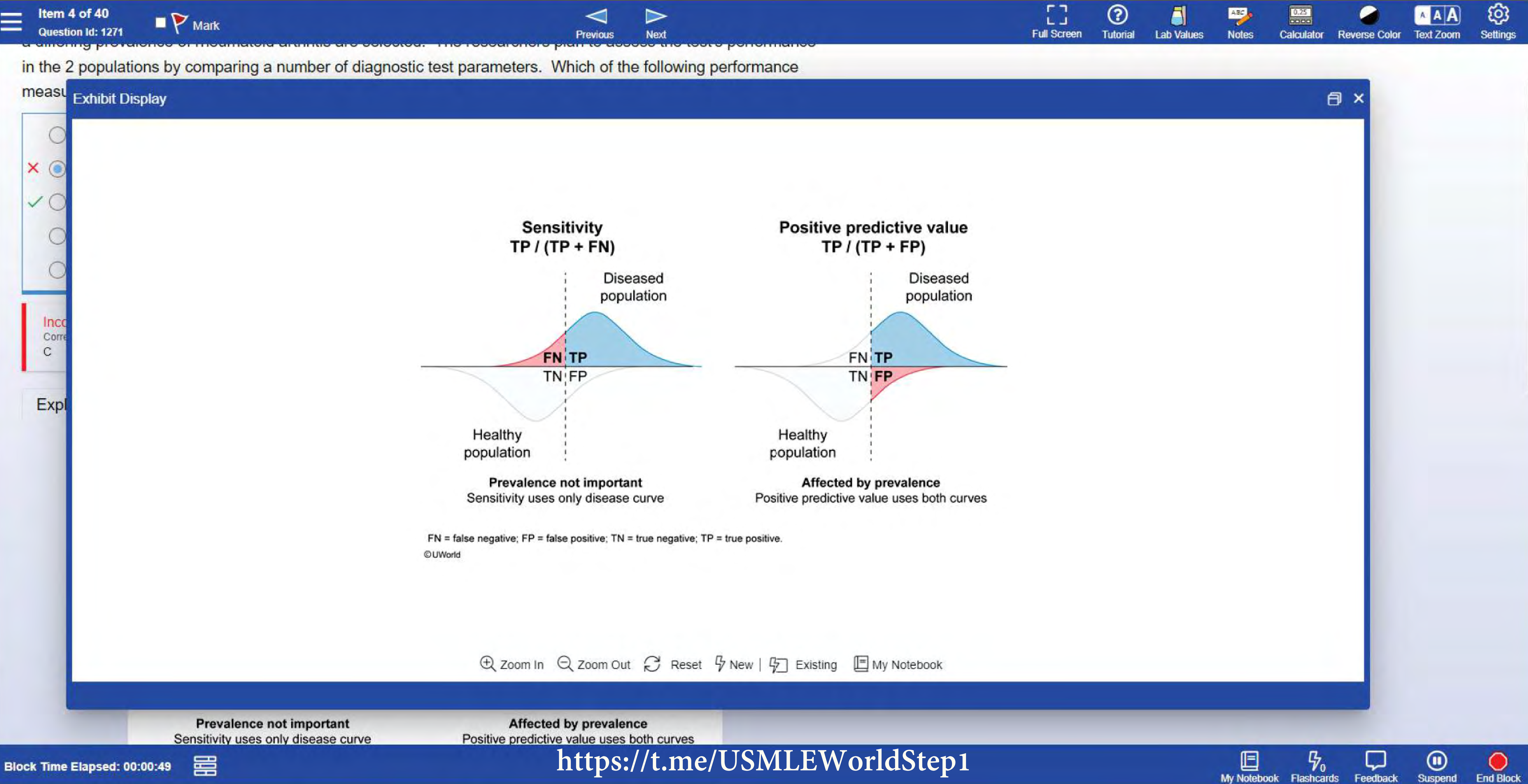
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a differing prevalence of rheumatoid arthritis are selected. The researchers plan to assess the test's performance in the 2 populations by comparing a number of diagnostic test parameters. Which of the following performance measu

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Sensitivity
TP / (TP + FN)

Diseased population
FN
TP
TN
FP
Healthy population

Prevalence not important
Sensitivity uses only disease curve

Positive predictive value
TP / (TP + FP)

Diseased population
FN
TP
TN
FP
Healthy population

Affected by prevalence
Positive predictive value uses both curves

FN = false negative; FP = false positive; TN = true negative; TP = true positive.

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Prevalence not important
Sensitivity uses only disease curve
Affected by prevalence
Positive predictive value uses both curves

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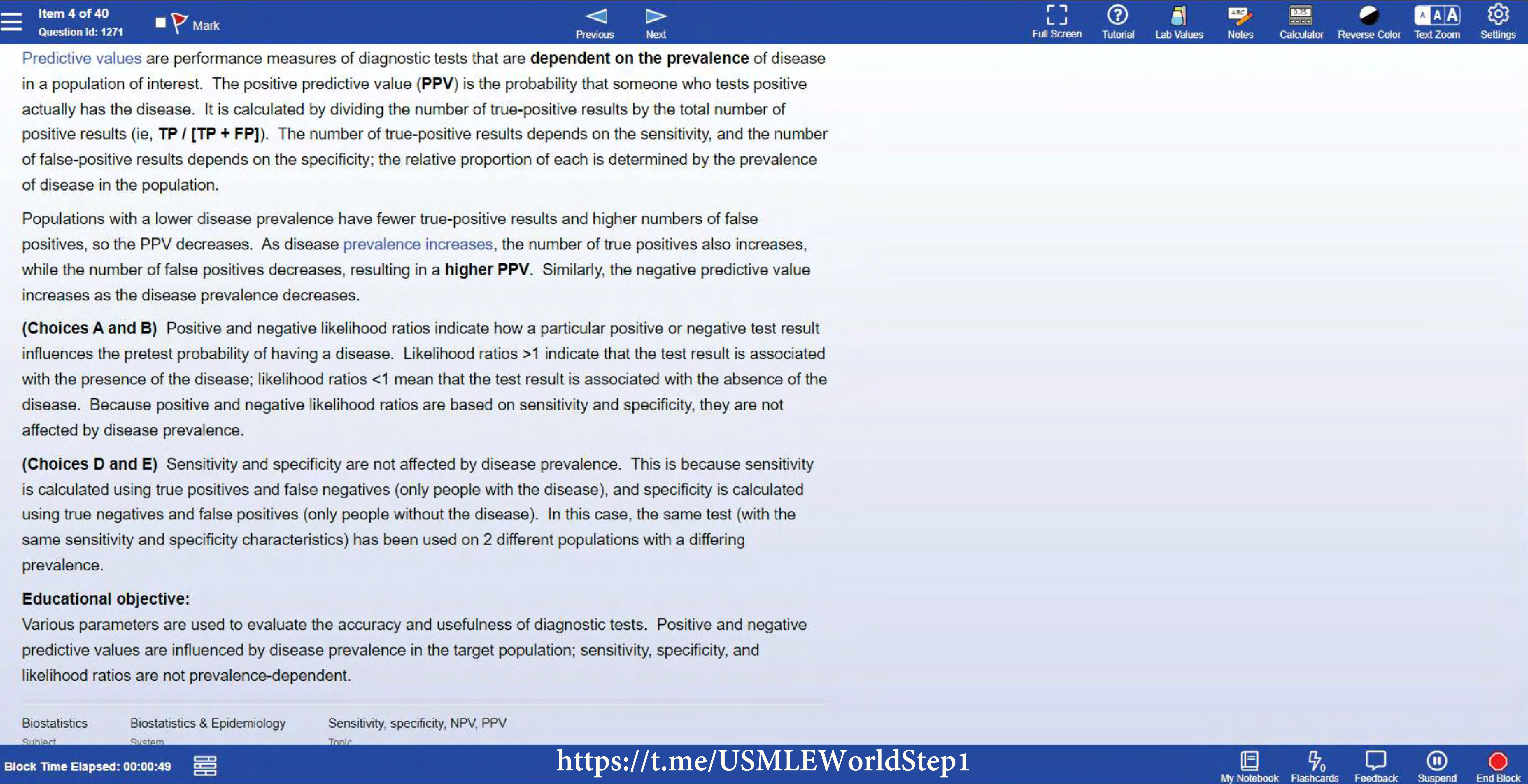

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Predictive values are performance measures of diagnostic tests that are **dependent on the prevalence** of disease in a population of interest. The positive predictive value (**PPV**) is the probability that someone who tests positive actually has the disease. It is calculated by dividing the number of true-positive results by the total number of positive results (ie, **TP / [TP + FP]**). The number of true-positive results depends on the sensitivity, and the number of false-positive results depends on the specificity; the relative proportion of each is determined by the prevalence of disease in the population.

Populations with a lower disease prevalence have fewer true-positive results and higher numbers of false positives, so the PPV decreases. As disease prevalence increases, the number of true positives also increases, while the number of false positives decreases, resulting in a **higher PPV**. Similarly, the negative predictive value increases as the disease prevalence decreases.

(Choices A and B) Positive and negative likelihood ratios indicate how a particular positive or negative test result influences the pretest probability of having a disease. Likelihood ratios >1 indicate that the test result is associated with the presence of the disease; likelihood ratios <1 mean that the test result is associated with the absence of the disease. Because positive and negative likelihood ratios are based on sensitivity and specificity, they are not affected by disease prevalence.

(Choices D and E) Sensitivity and specificity are not affected by disease prevalence. This is because sensitivity is calculated using true positives and false negatives (only people with the disease), and specificity is calculated using true negatives and false positives (only people without the disease). In this case, the same test (with the same sensitivity and specificity characteristics) has been used on 2 different populations with a differing prevalence.

Educational objective:

Various parameters are used to evaluate the accuracy and usefulness of diagnostic tests. Positive and negative predictive values are influenced by disease prevalence in the target population; sensitivity, specificity, and likelihood ratios are not prevalence-dependent.

Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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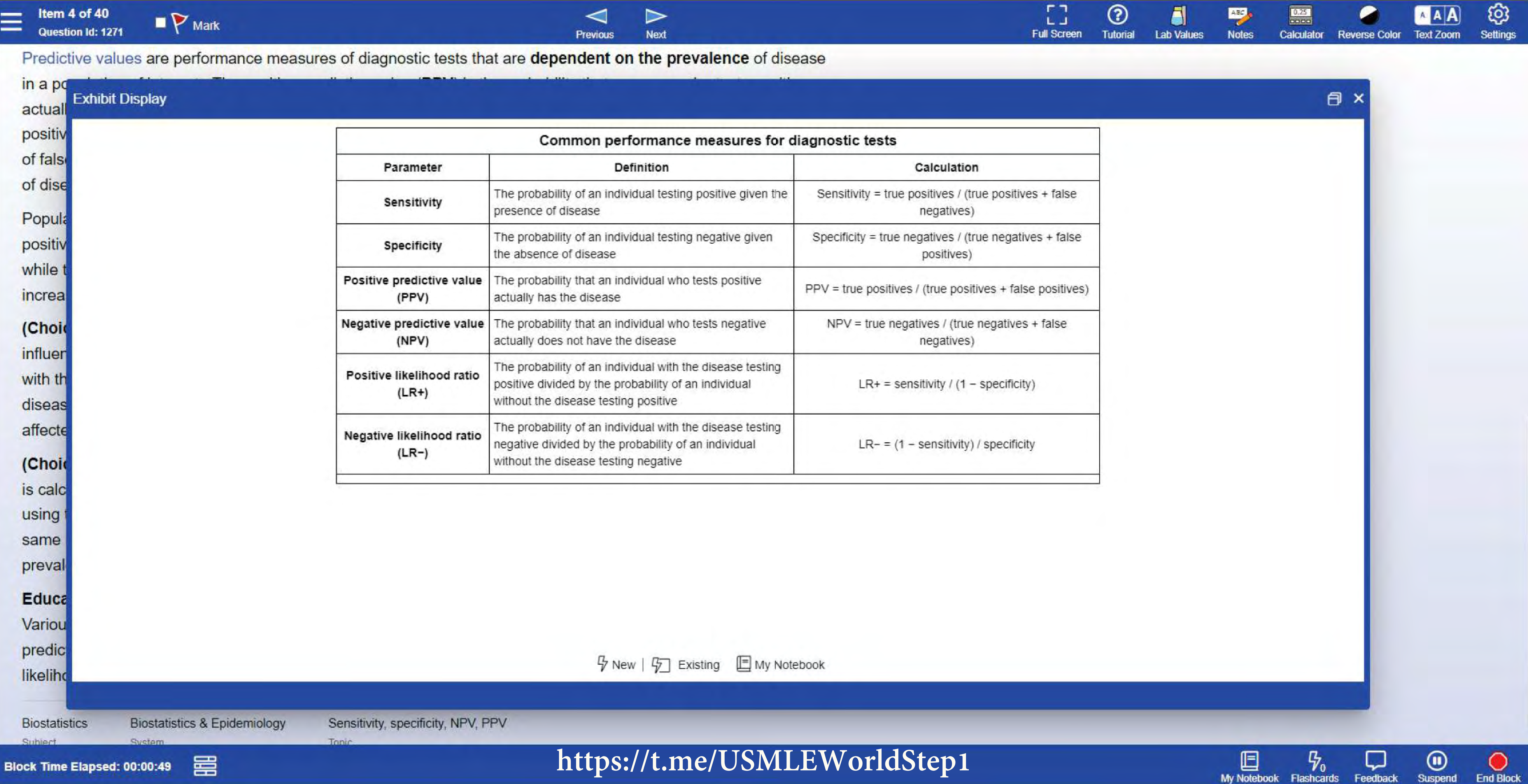

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Common performance measures for diagnostic tests		
Parameter	**Definition**	**Calculation**
Sensitivity	The probability of an individual testing positive given the presence of disease	Sensitivity = true positives / (true positives + false negatives)
Specificity	The probability of an individual testing negative given the absence of disease	Specificity = true negatives / (true negatives + false positives)
Positive predictive value (PPV)	The probability that an individual who tests positive actually has the disease	PPV = true positives / (true positives + false positives)
Negative predictive value (NPV)	The probability that an individual who tests negative actually does not have the disease	NPV = true negatives / (true negatives + false negatives)
Positive likelihood ratio (LR+)	The probability of an individual with the disease testing positive divided by the probability of an individual without the disease testing positive	LR+ = sensitivity / (1 − specificity)
Negative likelihood ratio (LR−)	The probability of an individual with the disease testing negative divided by the probability of an individual without the disease testing negative	LR− = (1 − sensitivity) / specificity

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Biostatistics & Epidemiology
System

Sensitivity, specificity, NPV, PPV
Topic

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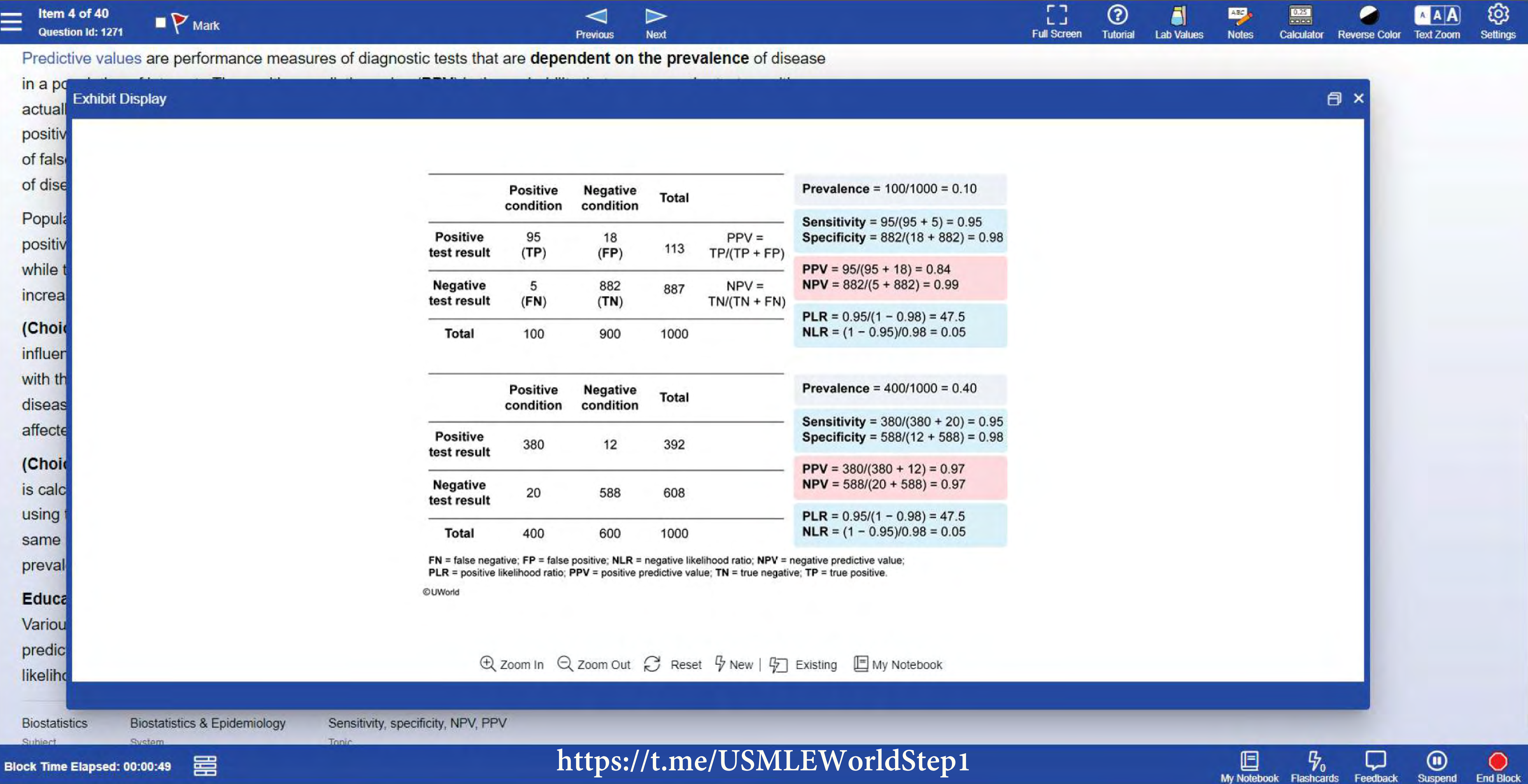
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	Positive condition	Negative condition	Total	
Positive test result	95 (**TP**)	18 (**FP**)	113	PPV = TP/(TP + FP)
Negative test result	5 (**FN**)	882 (**TN**)	887	NPV = TN/(TN + FN)
Total	100	900	1000	

Prevalence = 100/1000 = 0.10

Sensitivity = 95/(95 + 5) = 0.95
Specificity = 882/(18 + 882) = 0.98

PPV = 95/(95 + 18) = 0.84
NPV = 882/(5 + 882) = 0.99

PLR = 0.95/(1 − 0.98) = 47.5
NLR = (1 − 0.95)/0.98 = 0.05

	Positive condition	Negative condition	Total
Positive test result	380	12	392
Negative test result	20	588	608
Total	400	600	1000

Prevalence = 400/1000 = 0.40

Sensitivity = 380/(380 + 20) = 0.95
Specificity = 588/(12 + 588) = 0.98

PPV = 380/(380 + 12) = 0.97
NPV = 588/(20 + 588) = 0.97

PLR = 0.95/(1 − 0.98) = 47.5
NLR = (1 − 0.95)/0.98 = 0.05

FN = false negative; **FP** = false positive; **NLR** = negative likelihood ratio; **NPV** = negative predictive value; **PLR** = positive likelihood ratio; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

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Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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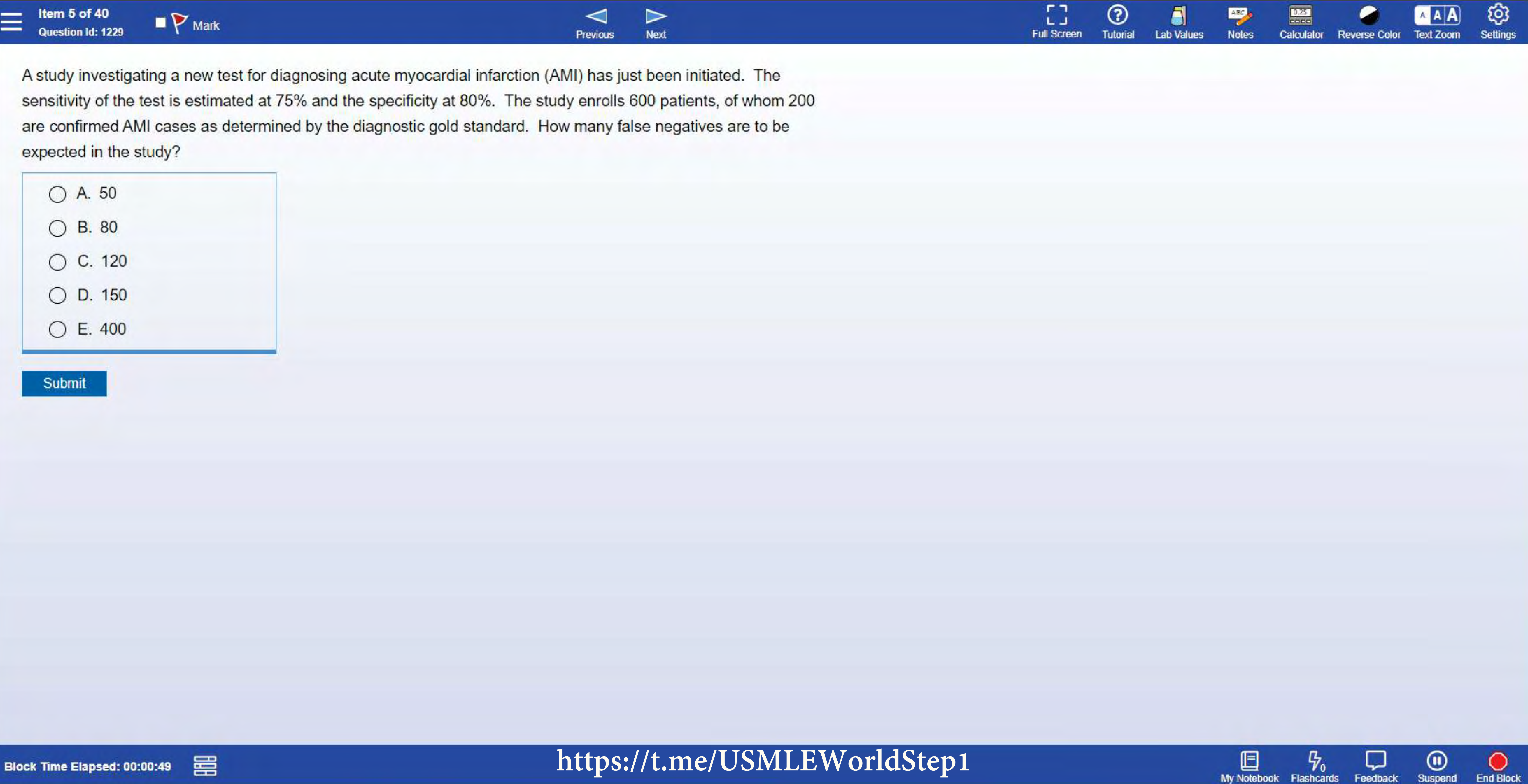

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A study investigating a new test for diagnosing acute myocardial infarction (AMI) has just been initiated. The sensitivity of the test is estimated at 75% and the specificity at 80%. The study enrolls 600 patients, of whom 200 are confirmed AMI cases as determined by the diagnostic gold standard. How many false negatives are to be expected in the study?

○ A. 50
○ B. 80
○ C. 120
○ D. 150
○ E. 400

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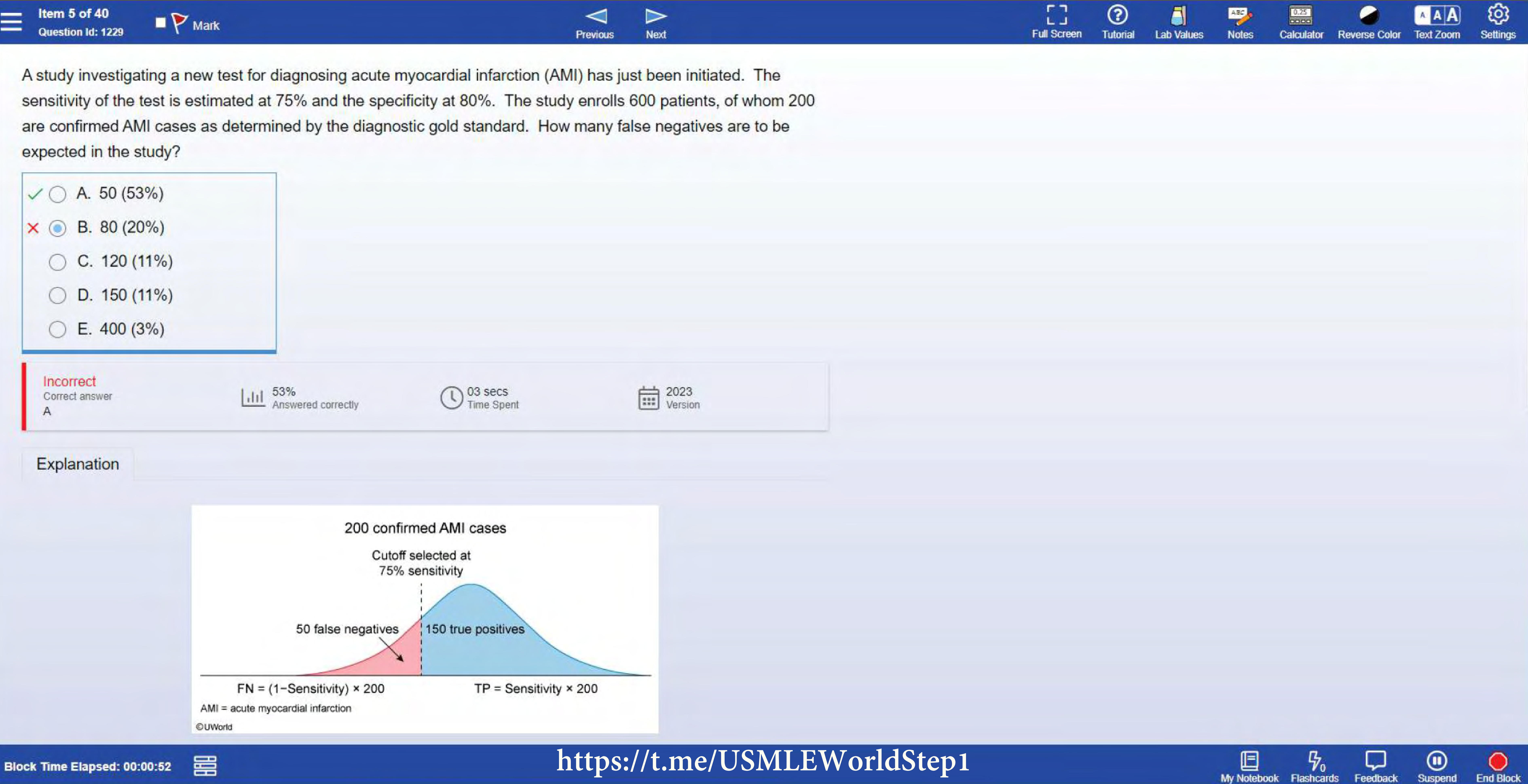

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- ✓ ○ A. 50 (53%)
- ✗ ● B. 80 (20%)
- ○ C. 120 (11%)
- ○ D. 150 (11%)
- ○ E. 400 (3%)

Incorrect
Correct answer
A

53%
Answered correctly

03 secs
Time Spent

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Explanation

200 confirmed AMI cases
Cutoff selected at
75% sensitivity
50 false negatives
150 true positives
FN = (1−Sensitivity) × 200
TP = Sensitivity × 200

AMI = acute myocardial infarction

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A study investigating a new test for diagnosing acute myocardial infarction (AMI) has just been initiated. The
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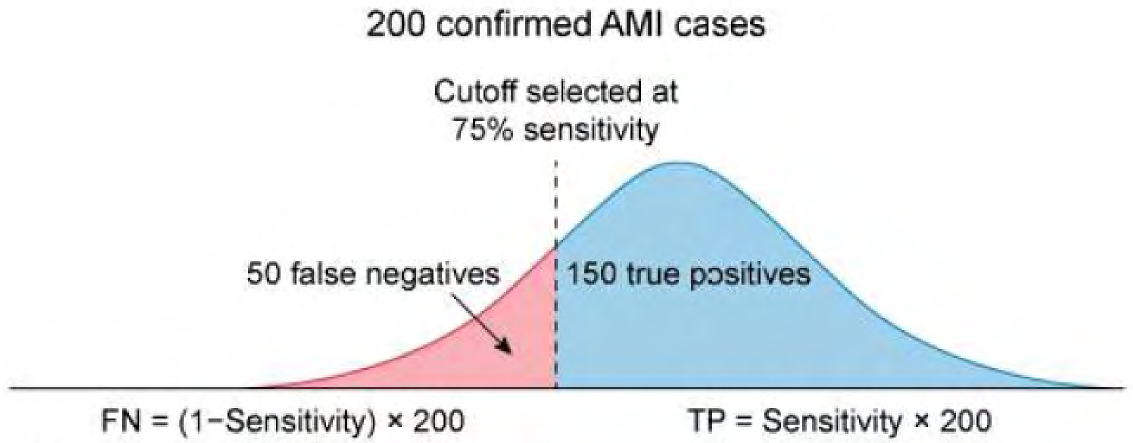

AMI = acute myocardial infarction

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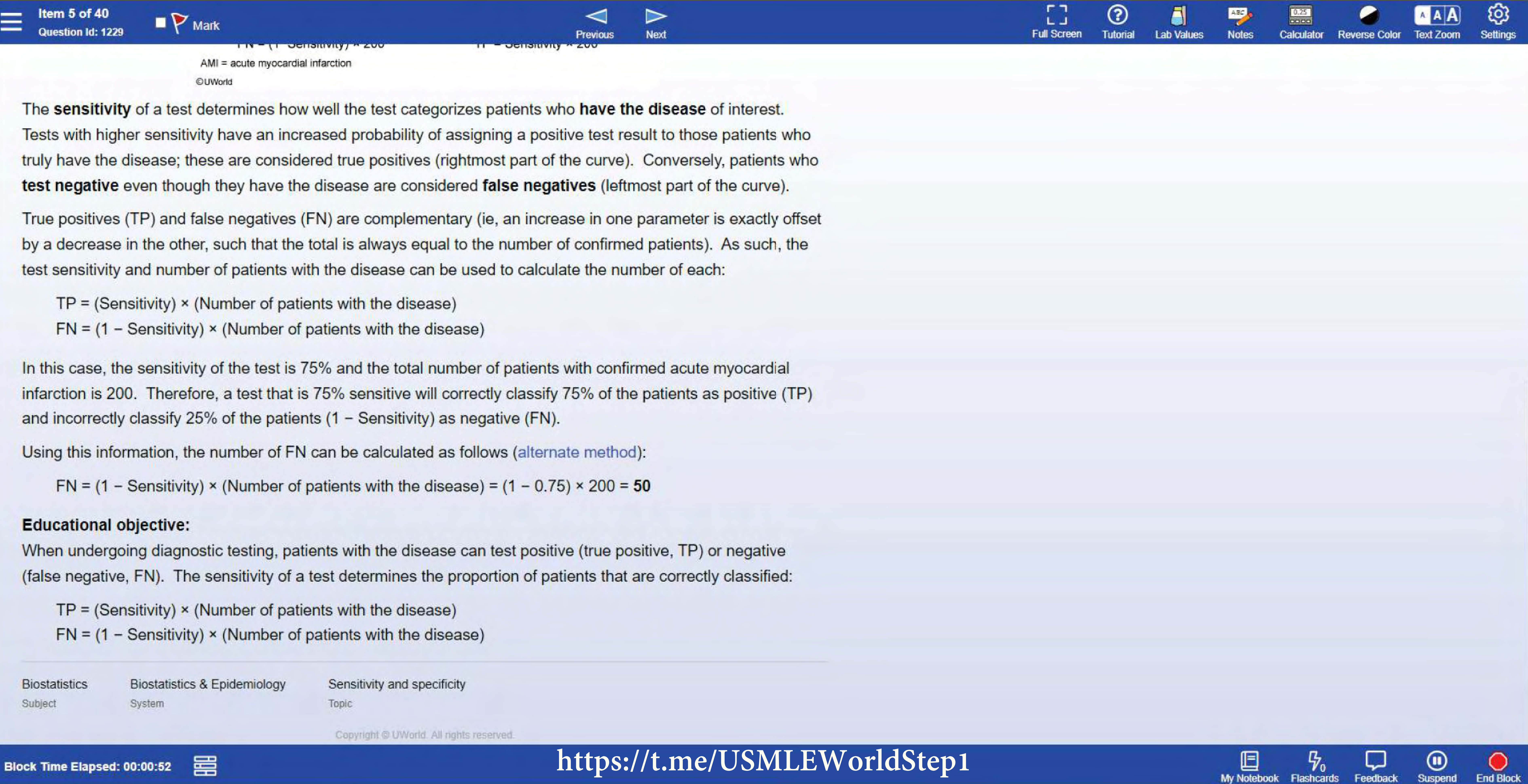

FN = (1 − Sensitivity) × 200 TP = Sensitivity × 200

AMI = acute myocardial infarction

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The **sensitivity** of a test determines how well the test categorizes patients who **have the disease** of interest. Tests with higher sensitivity have an increased probability of assigning a positive test result to those patients who truly have the disease; these are considered true positives (rightmost part of the curve). Conversely, patients who **test negative** even though they have the disease are considered **false negatives** (leftmost part of the curve).

True positives (TP) and false negatives (FN) are complementary (ie, an increase in one parameter is exactly offset by a decrease in the other, such that the total is always equal to the number of confirmed patients). As such, the test sensitivity and number of patients with the disease can be used to calculate the number of each:

TP = (Sensitivity) × (Number of patients with the disease)
FN = (1 − Sensitivity) × (Number of patients with the disease)

In this case, the sensitivity of the test is 75% and the total number of patients with confirmed acute myocardial infarction is 200. Therefore, a test that is 75% sensitive will correctly classify 75% of the patients as positive (TP) and incorrectly classify 25% of the patients (1 − Sensitivity) as negative (FN).

Using this information, the number of FN can be calculated as follows (alternate method):

FN = (1 − Sensitivity) × (Number of patients with the disease) = (1 − 0.75) × 200 = **50**

Educational objective:
When undergoing diagnostic testing, patients with the disease can test positive (true positive, TP) or negative (false negative, FN). The sensitivity of a test determines the proportion of patients that are correctly classified:

TP = (Sensitivity) × (Number of patients with the disease)
FN = (1 − Sensitivity) × (Number of patients with the disease)

Biostatistics	Biostatistics & Epidemiology	Sensitivity and specificity
Subject	System	Topic

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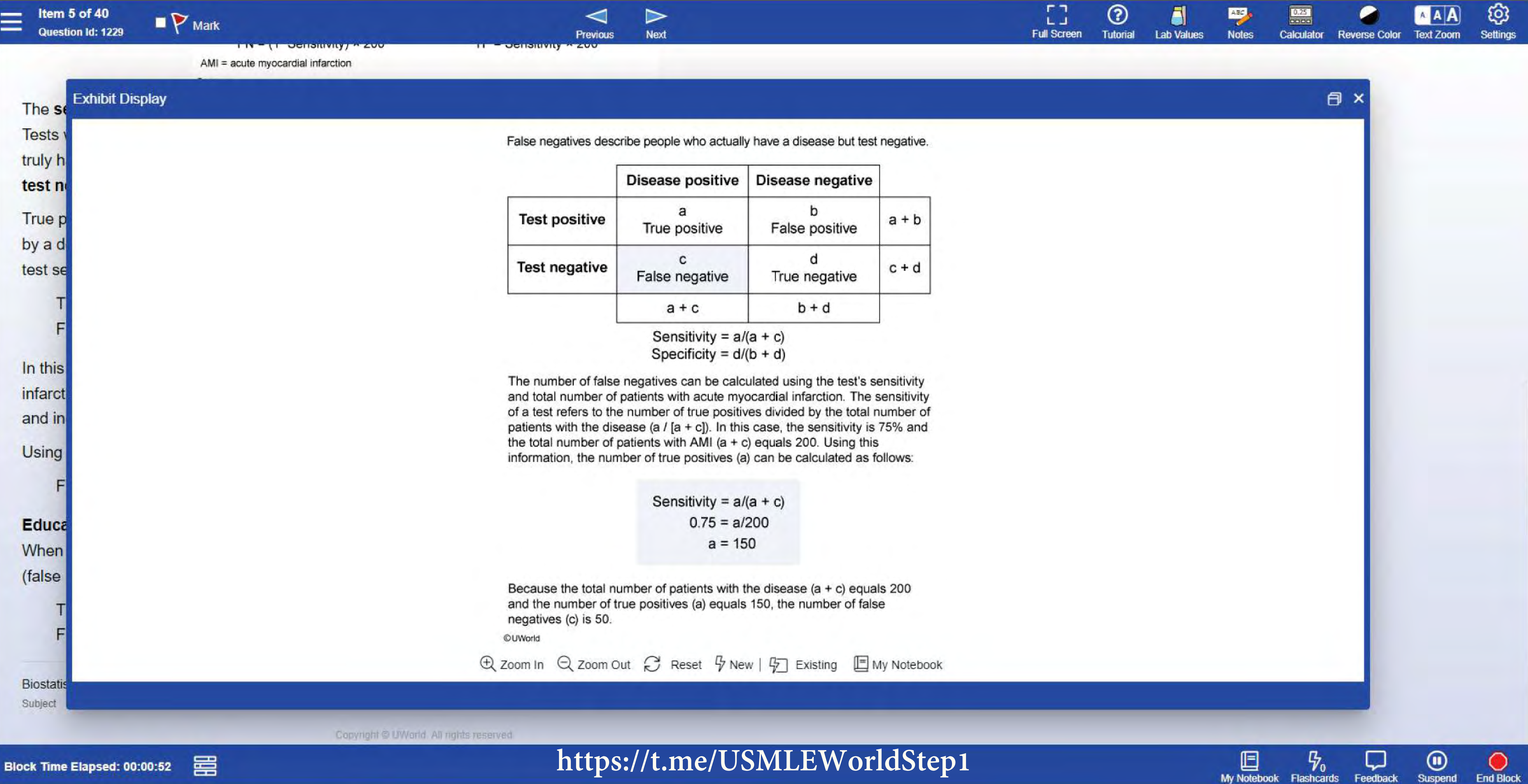
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AMI = acute myocardial infarction

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False negatives describe people who actually have a disease but test negative.

	Disease positive	Disease negative	
Test positive	a True positive	b False positive	a + b
Test negative	c False negative	d True negative	c + d
	a + c	b + d	

Sensitivity = a/(a + c)
Specificity = d/(b + d)

The number of false negatives can be calculated using the test's sensitivity and total number of patients with acute myocardial infarction. The sensitivity of a test refers to the number of true positives divided by the total number of patients with the disease (a / [a + c]). In this case, the sensitivity is 75% and the total number of patients with AMI (a + c) equals 200. Using this information, the number of true positives (a) can be calculated as follows:

$$\text{Sensitivity} = a/(a + c)$$
$$0.75 = a/200$$
$$a = 150$$

Because the total number of patients with the disease (a + c) equals 200 and the number of true positives (a) equals 150, the number of false negatives (c) is 50.

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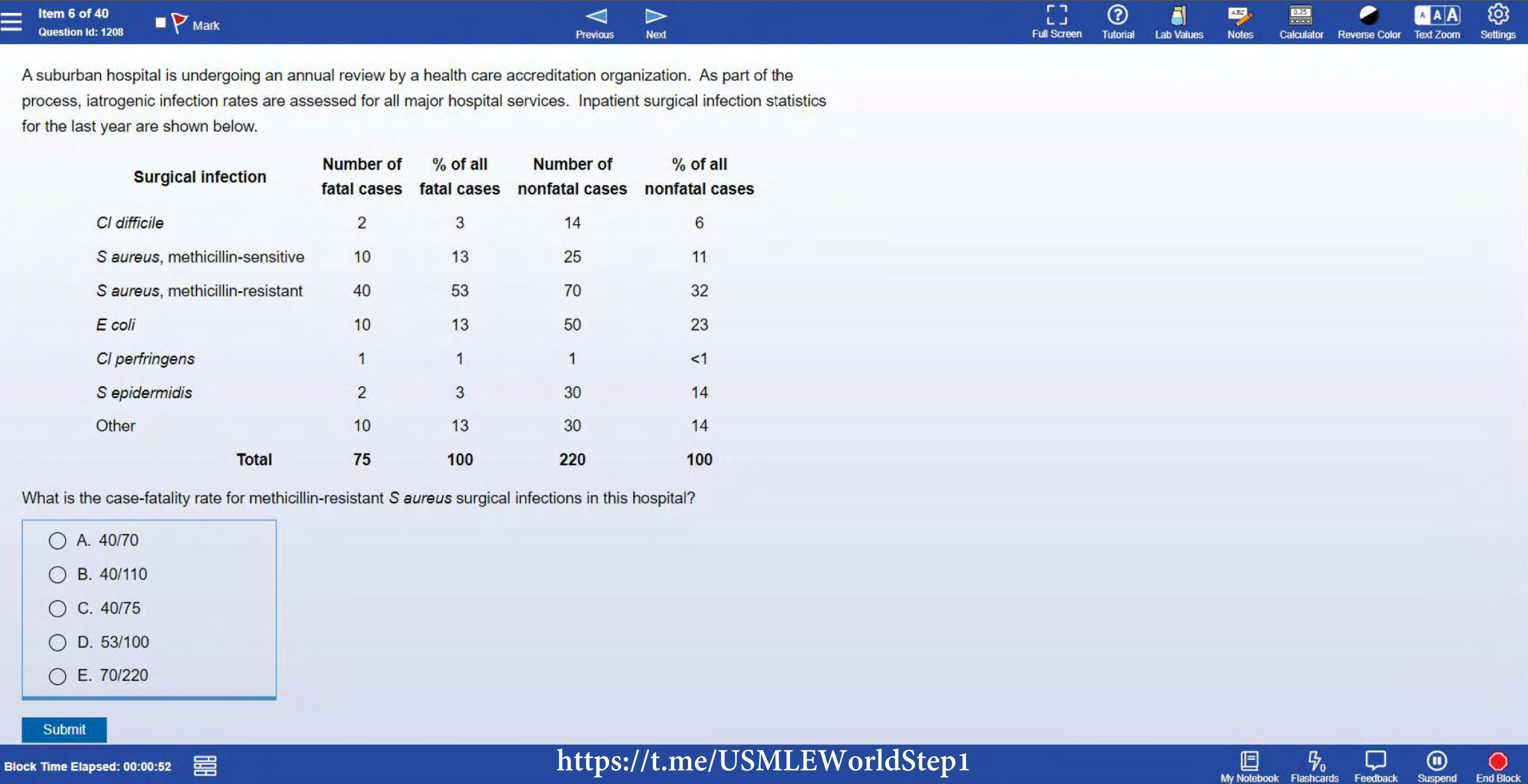
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A suburban hospital is undergoing an annual review by a health care accreditation organization. As part of the process, iatrogenic infection rates are assessed for all major hospital services. Inpatient surgical infection statistics for the last year are shown below.

Surgical infection	**Number of fatal cases**	**% of all fatal cases**	**Number of nonfatal cases**	**% of all nonfatal cases**
Cl difficile	2	3	14	6
S aureus, methicillin-sensitive	10	13	25	11
S aureus, methicillin-resistant	40	53	70	32
E coli	10	13	50	23
Cl perfringens	1	1	1	<1
S epidermidis	2	3	30	14
Other	10	13	30	14
Total	**75**	**100**	**220**	**100**

What is the case-fatality rate for methicillin-resistant *S aureus* surgical infections in this hospital?

○ A. 40/70

○ B. 40/110

○ C. 40/75

○ D. 53/100

○ E. 70/220

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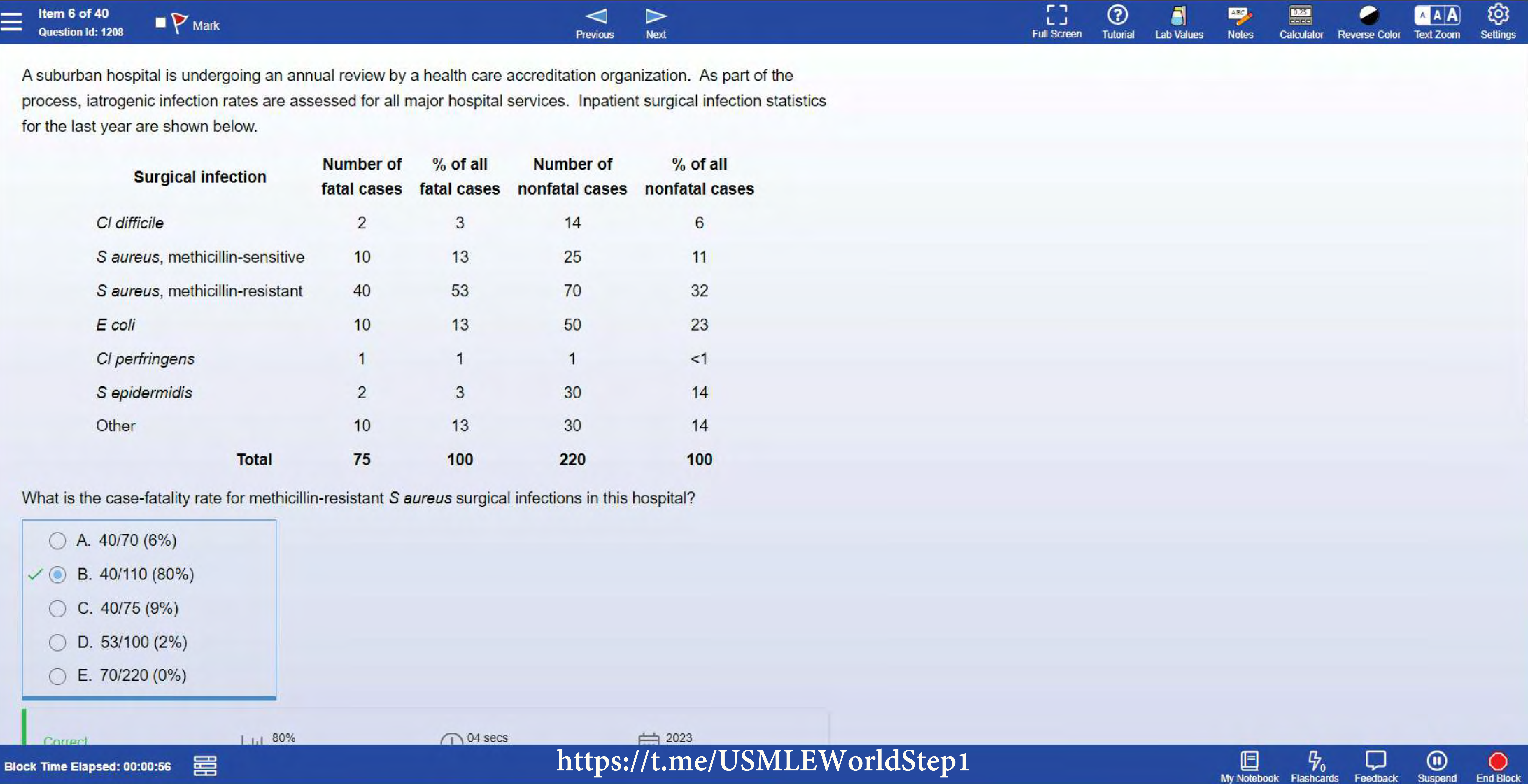
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Surgical infection	Number of fatal cases	% of all fatal cases	Number of nonfatal cases	% of all nonfatal cases
Cl difficile	2	3	14	6
S aureus, methicillin-sensitive	10	13	25	11
S aureus, methicillin-resistant	40	53	70	32
E coli	10	13	50	23
Cl perfringens	1	1	1	<1
S epidermidis	2	3	30	14
Other	10	13	30	14
Total	**75**	**100**	**220**	**100**

What is the case-fatality rate for methicillin-resistant *S aureus* surgical infections in this hospital?

○ A. 40/70 (6%)
✓ ● B. 40/110 (80%)
○ C. 40/75 (9%)
○ D. 53/100 (2%)
○ E. 70/220 (0%)

Correct 80% 04 secs 2023

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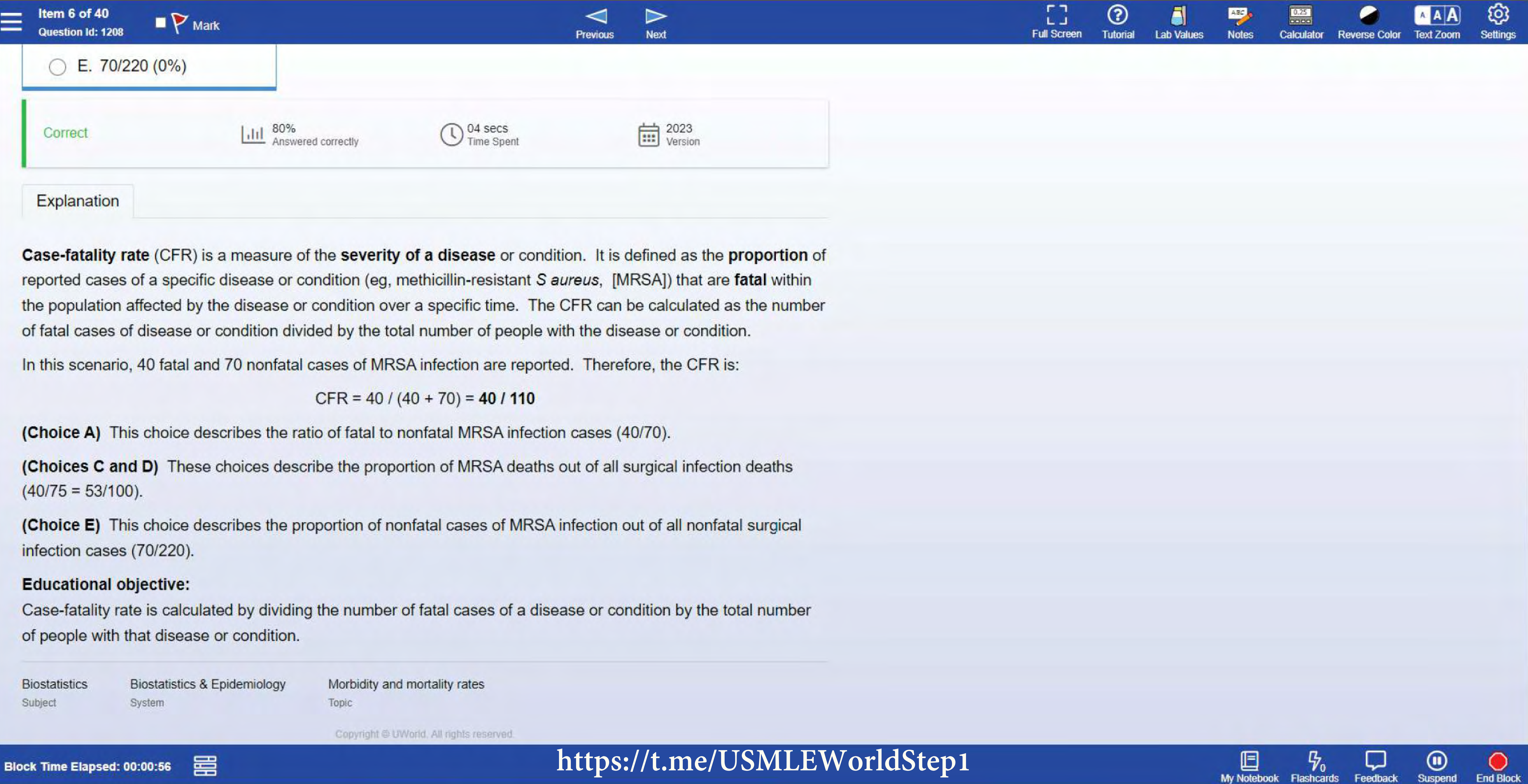
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○ E. 70/220 (0%)

Correct

80% Answered correctly

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Explanation

Case-fatality rate (CFR) is a measure of the **severity of a disease** or condition. It is defined as the **proportion** of reported cases of a specific disease or condition (eg, methicillin-resistant *S aureus*, [MRSA]) that are **fatal** within the population affected by the disease or condition over a specific time. The CFR can be calculated as the number of fatal cases of disease or condition divided by the total number of people with the disease or condition.

In this scenario, 40 fatal and 70 nonfatal cases of MRSA infection are reported. Therefore, the CFR is:

$$\text{CFR} = 40 / (40 + 70) = \mathbf{40 / 110}$$

(Choice A) This choice describes the ratio of fatal to nonfatal MRSA infection cases (40/70).

(Choices C and D) These choices describe the proportion of MRSA deaths out of all surgical infection deaths (40/75 = 53/100).

(Choice E) This choice describes the proportion of nonfatal cases of MRSA infection out of all nonfatal surgical infection cases (70/220).

Educational objective:
Case-fatality rate is calculated by dividing the number of fatal cases of a disease or condition by the total number of people with that disease or condition.

Biostatistics	Biostatistics & Epidemiology	Morbidity and mortality rates
Subject	System	Topic

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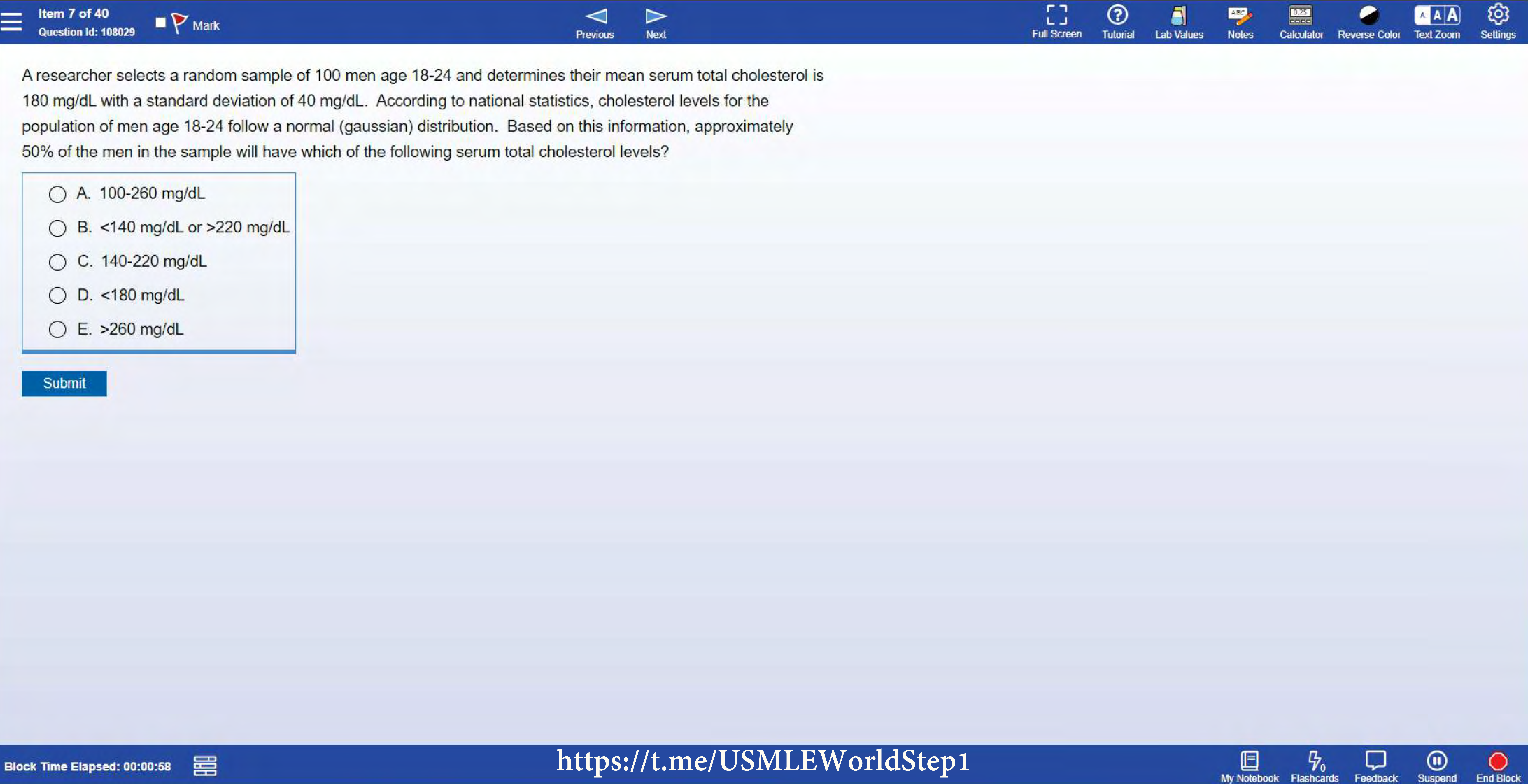
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A researcher selects a random sample of 100 men age 18-24 and determines their mean serum total cholesterol is 180 mg/dL with a standard deviation of 40 mg/dL. According to national statistics, cholesterol levels for the population of men age 18-24 follow a normal (gaussian) distribution. Based on this information, approximately 50% of the men in the sample will have which of the following serum total cholesterol levels?

○ A. 100-260 mg/dL
○ B. <140 mg/dL or >220 mg/dL
○ C. 140-220 mg/dL
○ D. <180 mg/dL
○ E. >260 mg/dL

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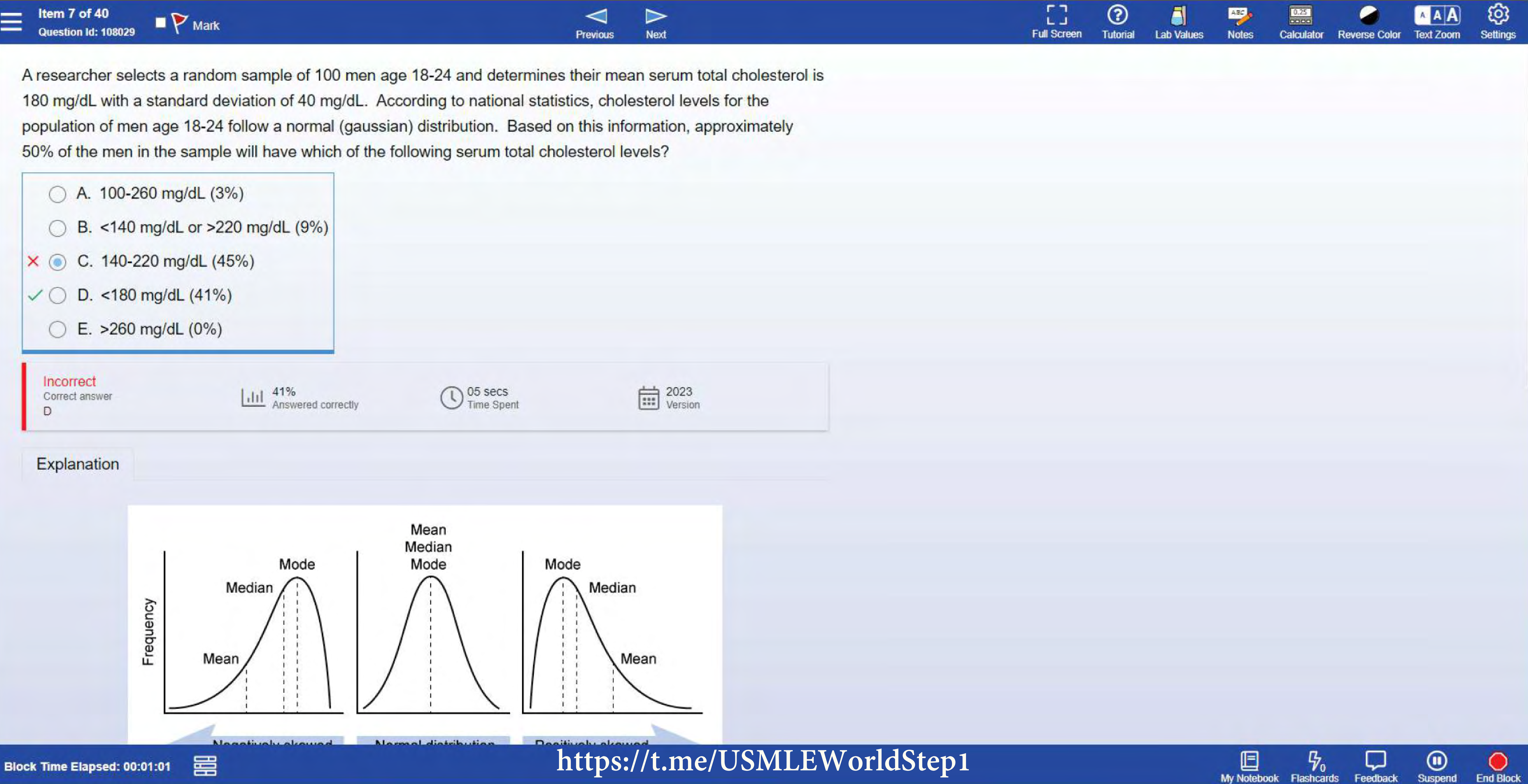
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A researcher selects a random sample of 100 men age 18-24 and determines their mean serum total cholesterol is 180 mg/dL with a standard deviation of 40 mg/dL. According to national statistics, cholesterol levels for the population of men age 18-24 follow a normal (gaussian) distribution. Based on this information, approximately 50% of the men in the sample will have which of the following serum total cholesterol levels?

○ A. 100-260 mg/dL (3%)
○ B. <140 mg/dL or >220 mg/dL (9%)
✗ ● C. 140-220 mg/dL (45%)
✓ ○ D. <180 mg/dL (41%)
○ E. >260 mg/dL (0%)

Incorrect
Correct answer
D

41%
Answered correctly

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Explanation

Frequency
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Normal distribution
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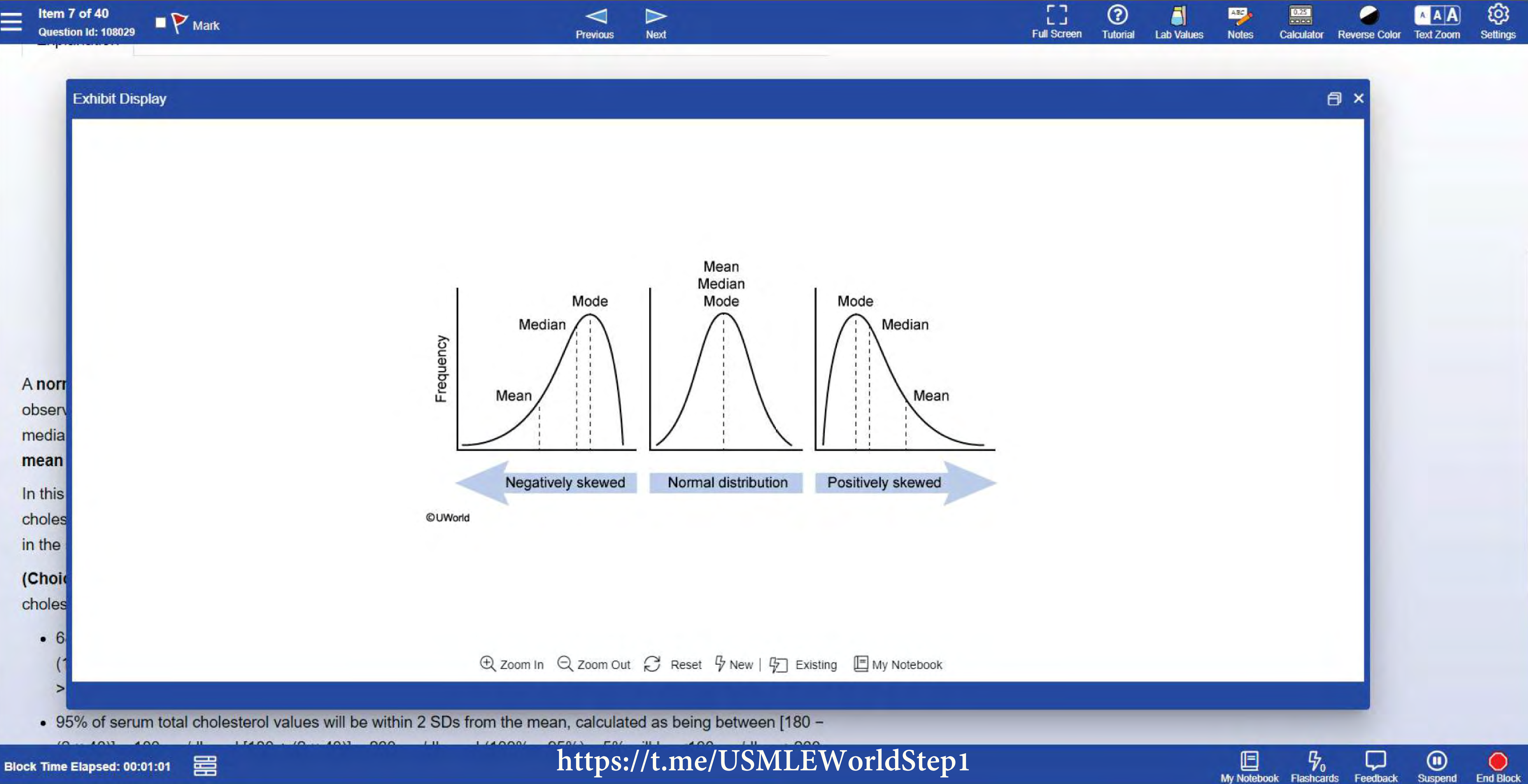
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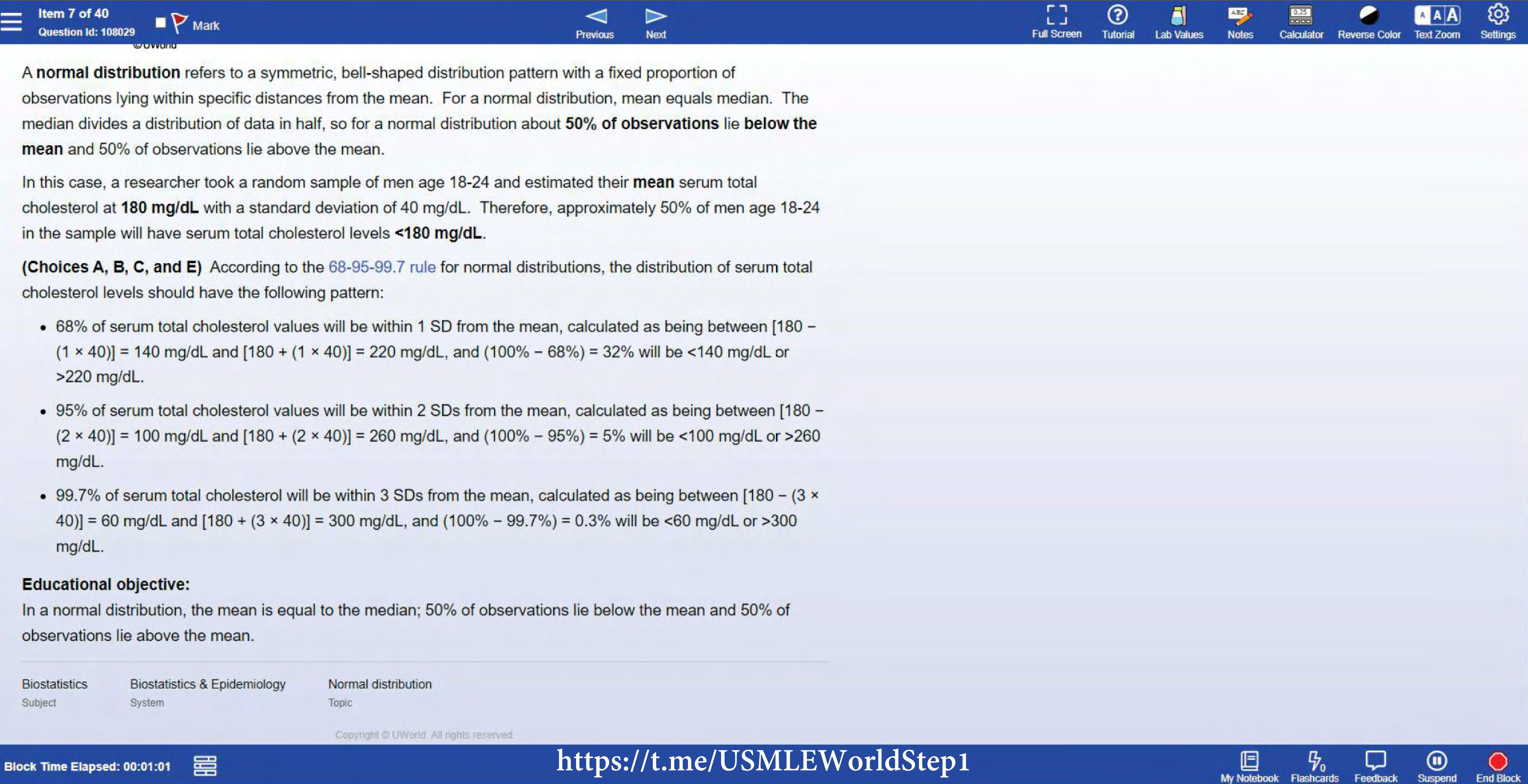
- 95% of serum total cholesterol values will be within 2 SDs from the mean, calculated as being between [180 –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A **normal distribution** refers to a symmetric, bell-shaped distribution pattern with a fixed proportion of observations lying within specific distances from the mean. For a normal distribution, mean equals median. The median divides a distribution of data in half, so for a normal distribution about **50% of observations** lie **below the mean** and 50% of observations lie above the mean.

In this case, a researcher took a random sample of men age 18-24 and estimated their **mean** serum total cholesterol at **180 mg/dL** with a standard deviation of 40 mg/dL. Therefore, approximately 50% of men age 18-24 in the sample will have serum total cholesterol levels **<180 mg/dL**.

(Choices A, B, C, and E) According to the 68-95-99.7 rule for normal distributions, the distribution of serum total cholesterol levels should have the following pattern:

- 68% of serum total cholesterol values will be within 1 SD from the mean, calculated as being between [180 − (1 × 40)] = 140 mg/dL and [180 + (1 × 40)] = 220 mg/dL, and (100% − 68%) = 32% will be <140 mg/dL or >220 mg/dL.
- 95% of serum total cholesterol values will be within 2 SDs from the mean, calculated as being between [180 − (2 × 40)] = 100 mg/dL and [180 + (2 × 40)] = 260 mg/dL, and (100% − 95%) = 5% will be <100 mg/dL or >260 mg/dL.
- 99.7% of serum total cholesterol will be within 3 SDs from the mean, calculated as being between [180 − (3 × 40)] = 60 mg/dL and [180 + (3 × 40)] = 300 mg/dL, and (100% − 99.7%) = 0.3% will be <60 mg/dL or >300 mg/dL.

Educational objective:
In a normal distribution, the mean is equal to the median; 50% of observations lie below the mean and 50% of observations lie above the mean.

Biostatistics	Biostatistics & Epidemiology	Normal distribution
Subject	System	Topic

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A **normal distribution** refers to a symmetric, bell-shaped distribution pattern with a fixed proportion of

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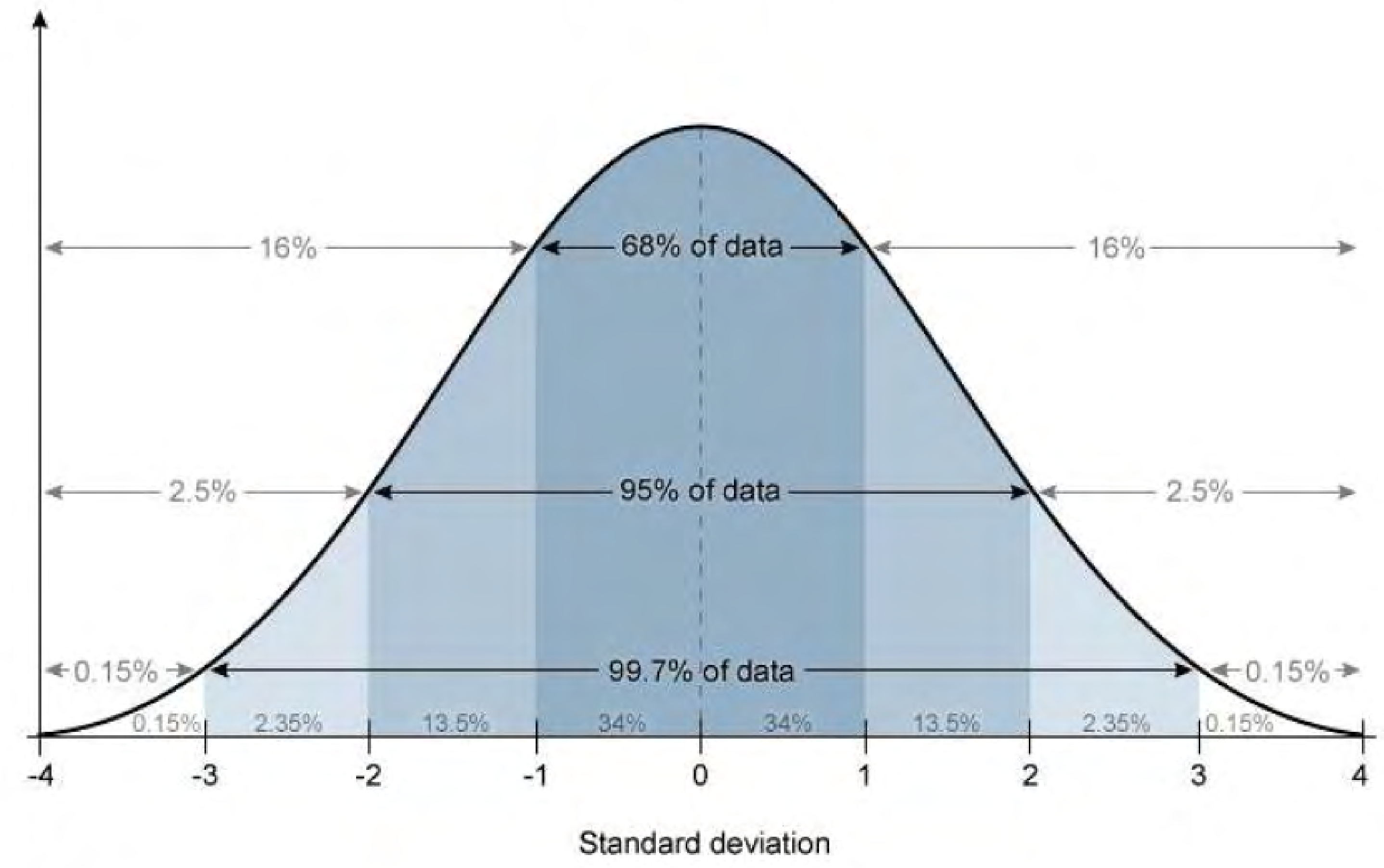
68-95-99.7 rule



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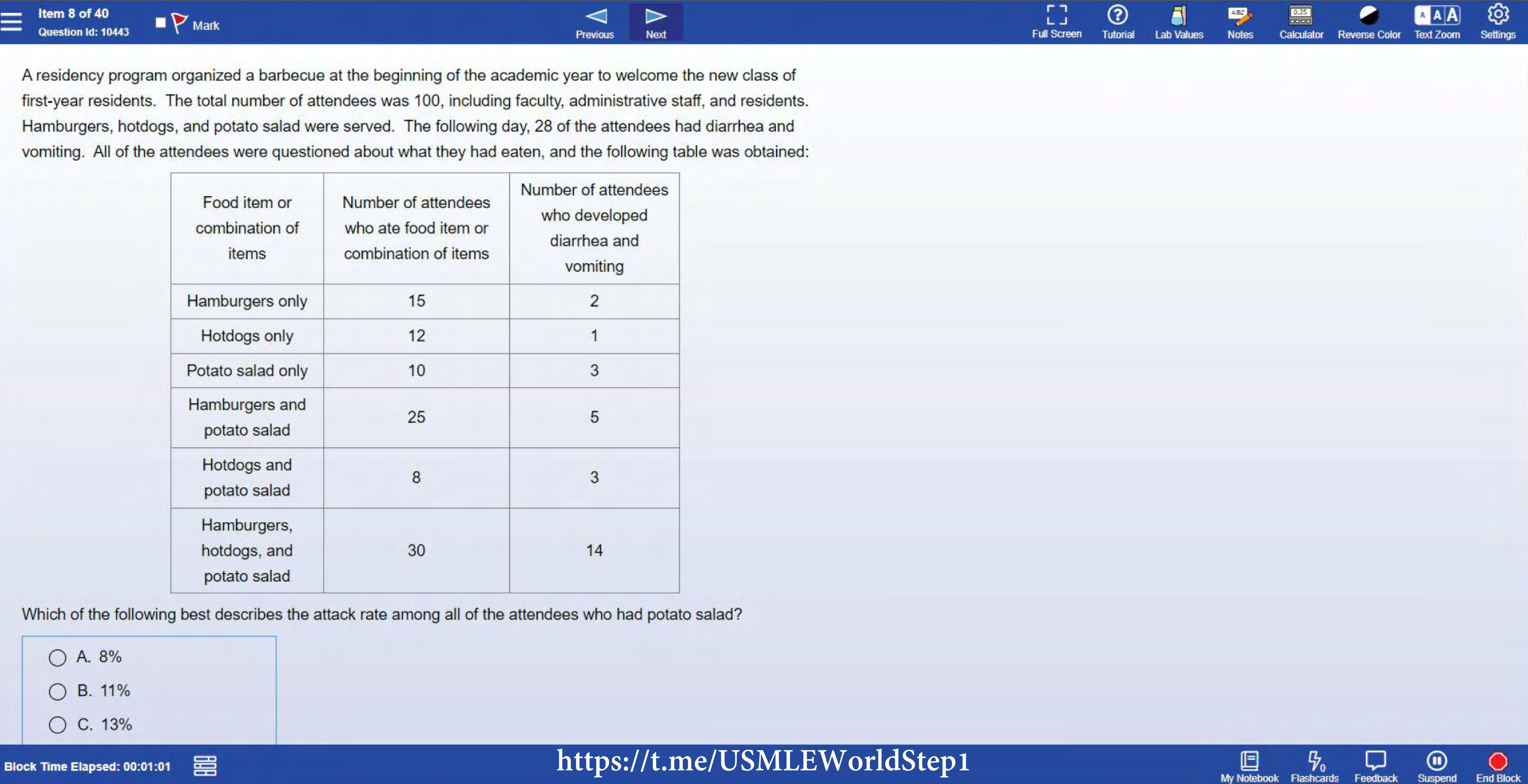
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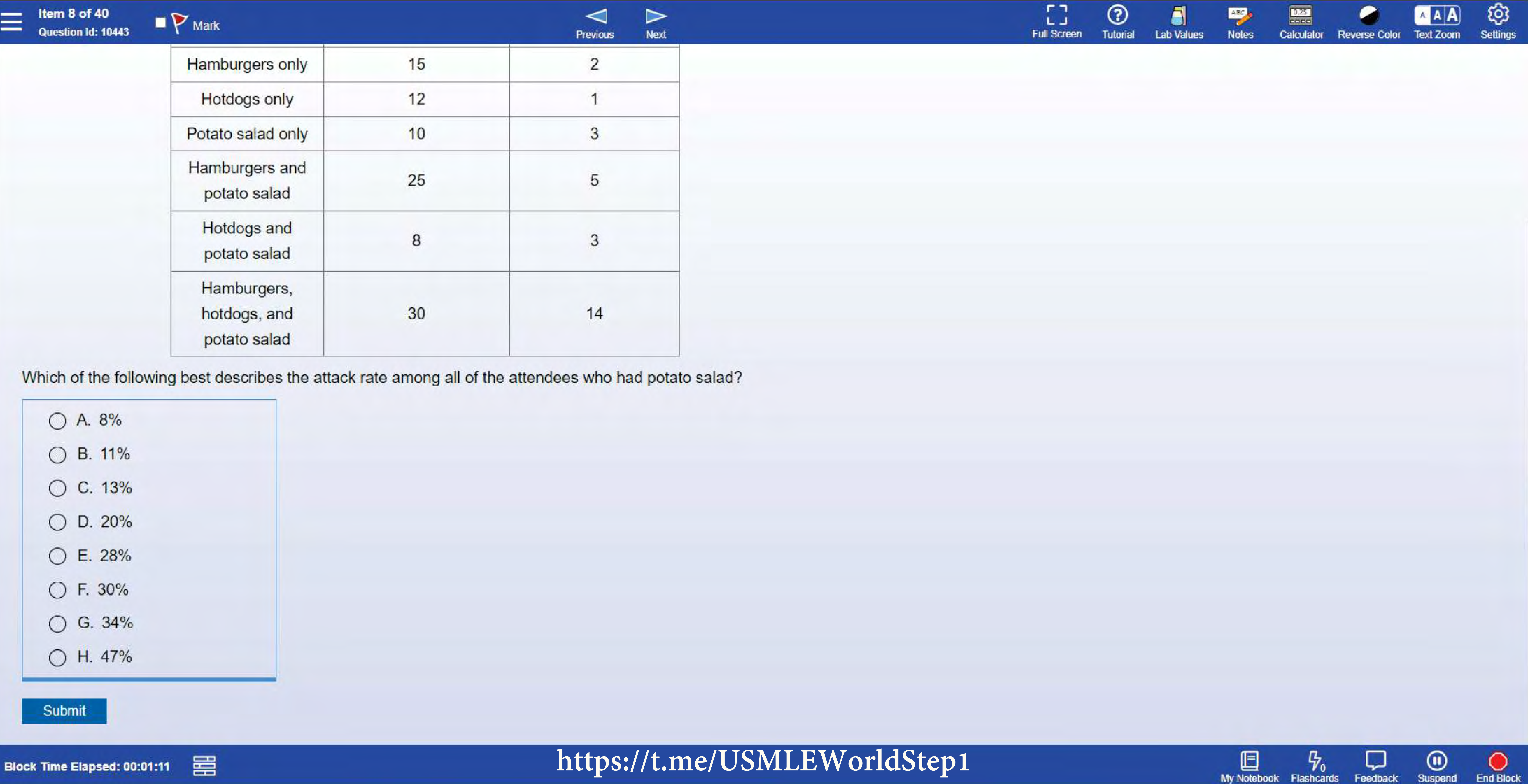
A residency program organized a barbecue at the beginning of the academic year to welcome the new class of first-year residents. The total number of attendees was 100, including faculty, administrative staff, and residents. Hamburgers, hotdogs, and potato salad were served. The following day, 28 of the attendees had diarrhea and vomiting. All of the attendees were questioned about what they had eaten, and the following table was obtained:

Food item or combination of items	Number of attendees who ate food item or combination of items	Number of attendees who developed diarrhea and vomiting
Hamburgers only	15	2
Hotdogs only	12	1
Potato salad only	10	3
Hamburgers and potato salad	25	5
Hotdogs and potato salad	8	3
Hamburgers, hotdogs, and potato salad	30	14

Which of the following best describes the attack rate among all of the attendees who had potato salad?

○ A. 8%
○ B. 11%
○ C. 13%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Hamburgers only	15	2
Hotdogs only	12	1
Potato salad only	10	3
Hamburgers and potato salad	25	5
Hotdogs and potato salad	8	3
Hamburgers, hotdogs, and potato salad	30	14

Which of the following best describes the attack rate among all of the attendees who had potato salad?

○ A. 8%
○ B. 11%
○ C. 13%
○ D. 20%
○ E. 28%
○ F. 30%
○ G. 34%
○ H. 47%

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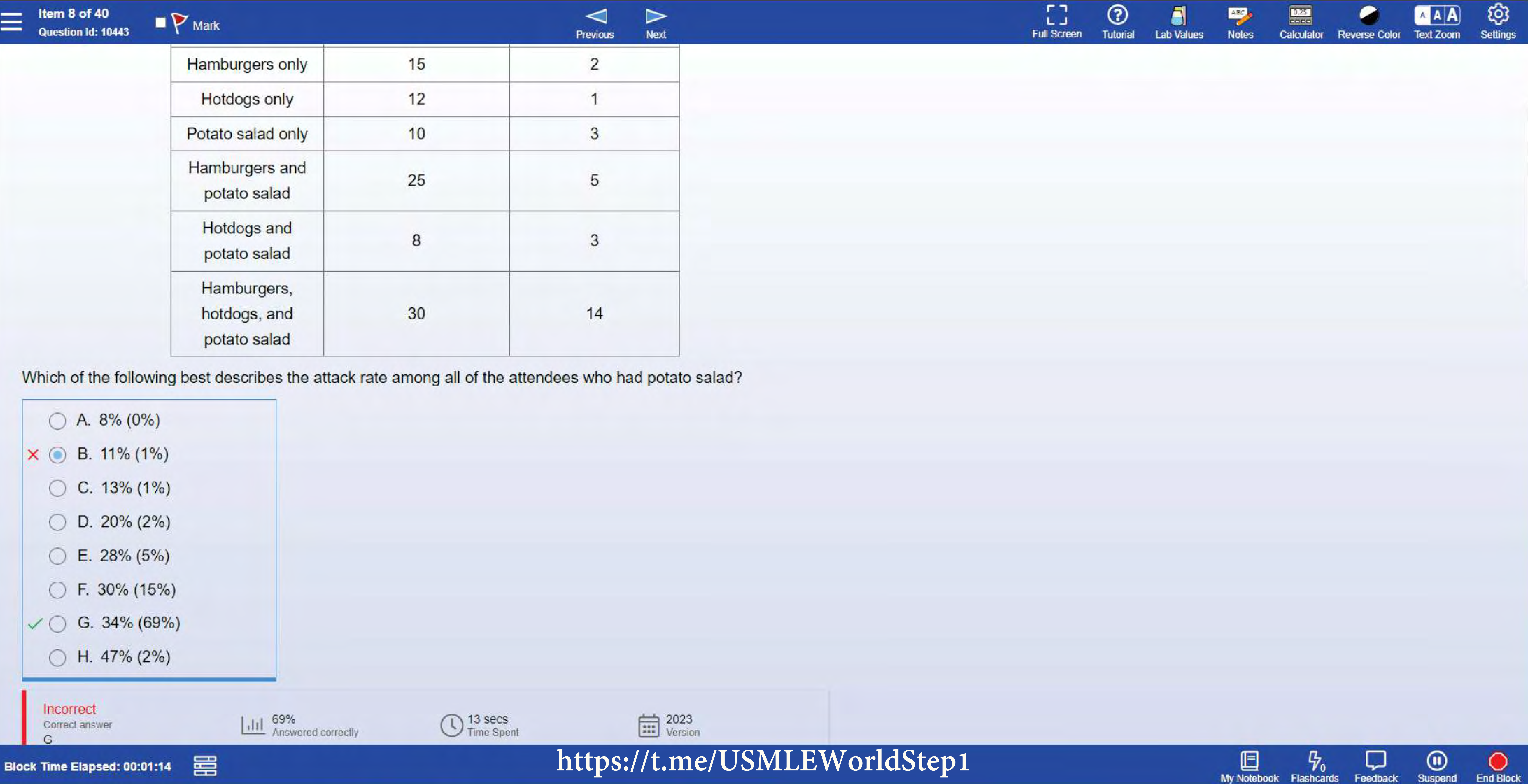
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Hamburgers only	15	2
Hotdogs only	12	1
Potato salad only	10	3
Hamburgers and potato salad	25	5
Hotdogs and potato salad	8	3
Hamburgers, hotdogs, and potato salad	30	14

Which of the following best describes the attack rate among all of the attendees who had potato salad?

- ○ A. 8% (0%)
- ✗ ● B. 11% (1%)
- ○ C. 13% (1%)
- ○ D. 20% (2%)
- ○ E. 28% (5%)
- ○ F. 30% (15%)
- ✓ ○ G. 34% (69%)
- ○ H. 47% (2%)

Incorrect
Correct answer
G

69%
Answered correctly

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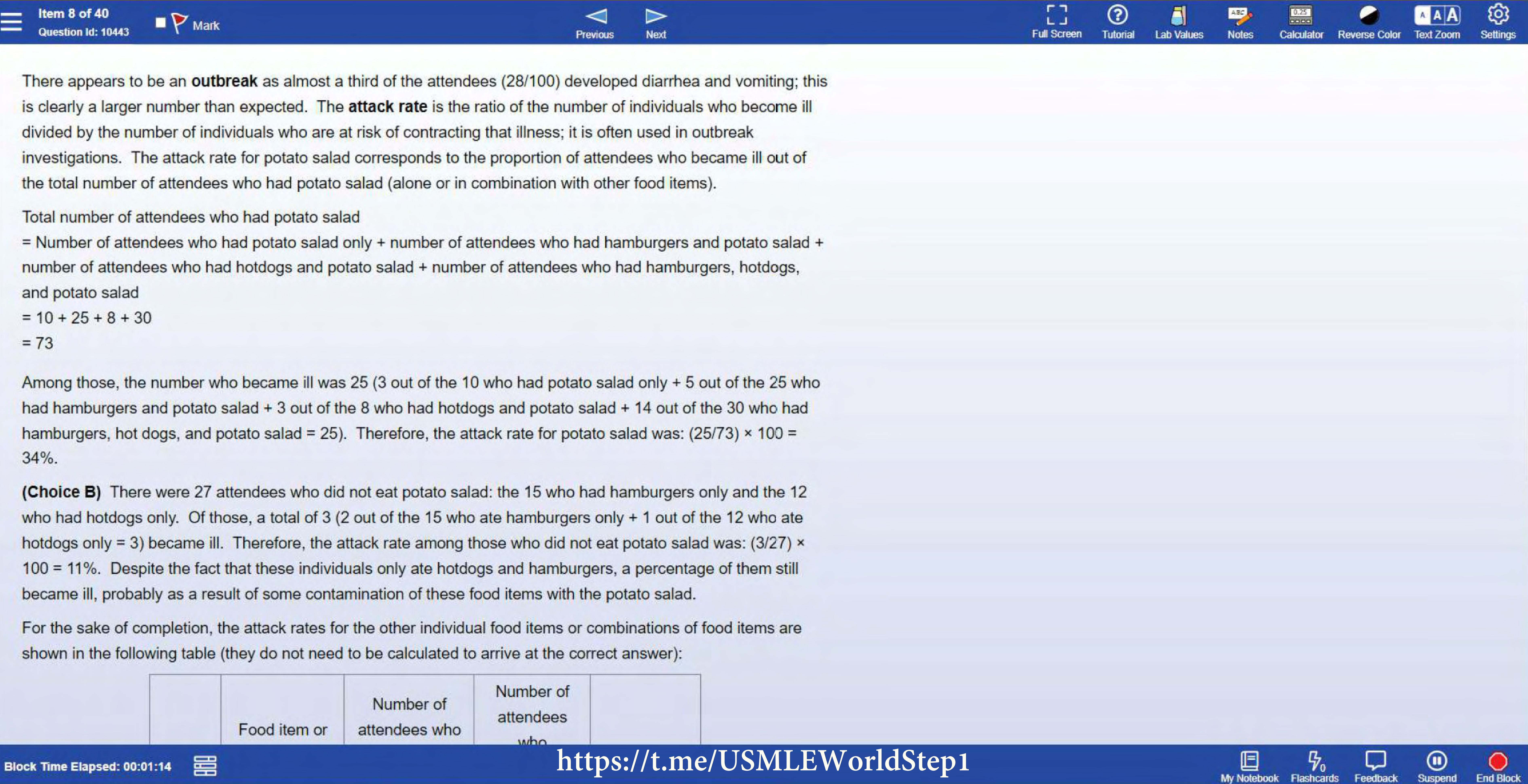
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There appears to be an **outbreak** as almost a third of the attendees (28/100) developed diarrhea and vomiting; this is clearly a larger number than expected. The **attack rate** is the ratio of the number of individuals who become ill divided by the number of individuals who are at risk of contracting that illness; it is often used in outbreak investigations. The attack rate for potato salad corresponds to the proportion of attendees who became ill out of the total number of attendees who had potato salad (alone or in combination with other food items).

Total number of attendees who had potato salad
= Number of attendees who had potato salad only + number of attendees who had hamburgers and potato salad + number of attendees who had hotdogs and potato salad + number of attendees who had hamburgers, hotdogs, and potato salad
= 10 + 25 + 8 + 30
= 73

Among those, the number who became ill was 25 (3 out of the 10 who had potato salad only + 5 out of the 25 who had hamburgers and potato salad + 3 out of the 8 who had hotdogs and potato salad + 14 out of the 30 who had hamburgers, hot dogs, and potato salad = 25). Therefore, the attack rate for potato salad was: (25/73) × 100 = 34%.

(Choice B) There were 27 attendees who did not eat potato salad: the 15 who had hamburgers only and the 12 who had hotdogs only. Of those, a total of 3 (2 out of the 15 who ate hamburgers only + 1 out of the 12 who ate hotdogs only = 3) became ill. Therefore, the attack rate among those who did not eat potato salad was: (3/27) × 100 = 11%. Despite the fact that these individuals only ate hotdogs and hamburgers, a percentage of them still became ill, probably as a result of some contamination of these food items with the potato salad.

For the sake of completion, the attack rates for the other individual food items or combinations of food items are shown in the following table (they do not need to be calculated to arrive at the correct answer):

	Food item or	Number of attendees who	Number of attendees who	

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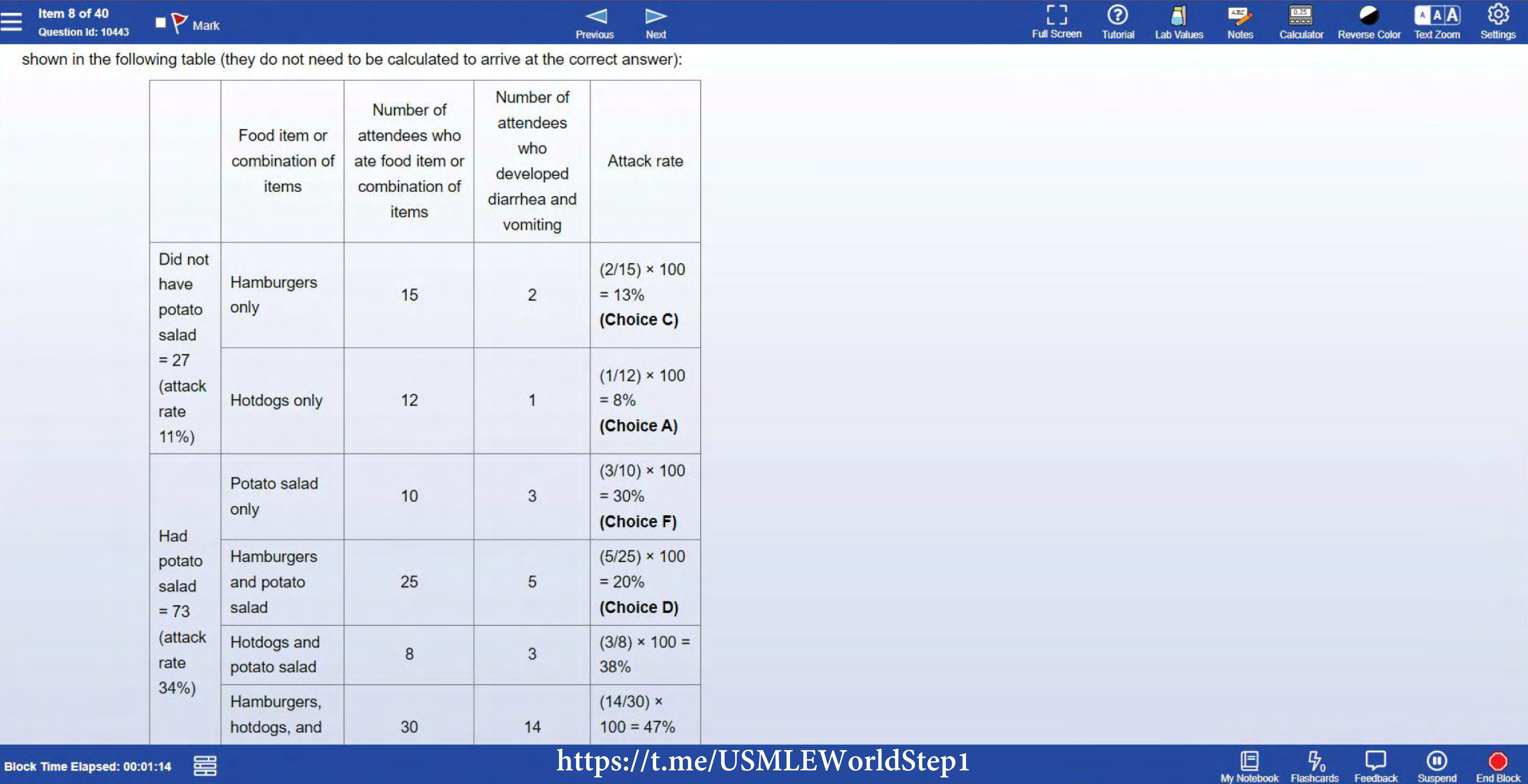
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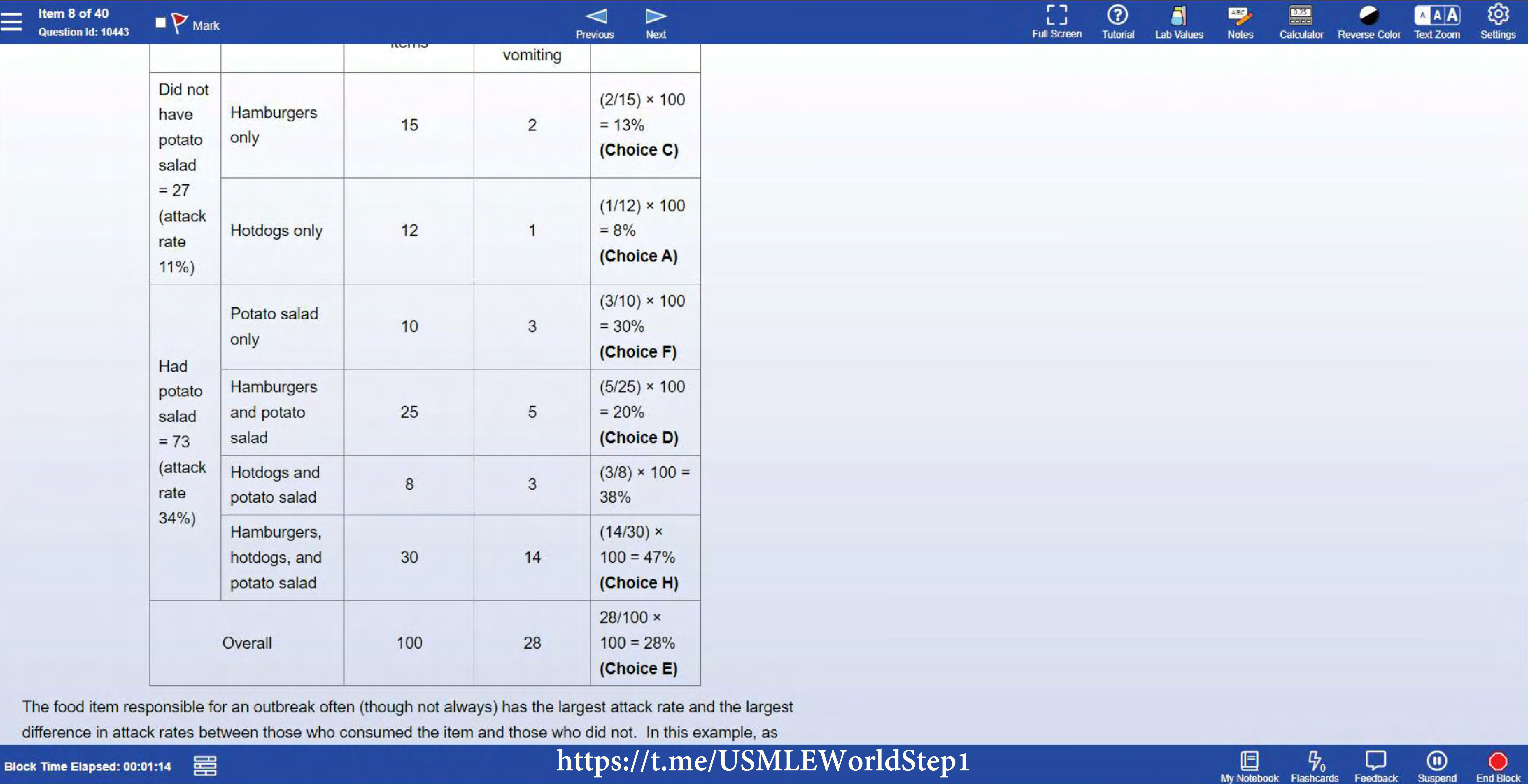
shown in the following table (they do not need to be calculated to arrive at the correct answer):

	Food item or combination of items	Number of attendees who ate food item or combination of items	Number of attendees who developed diarrhea and vomiting	Attack rate
Did not have potato salad = 27 (attack rate 11%)	Hamburgers only	15	2	(2/15) × 100 = 13% **(Choice C)**
	Hotdogs only	12	1	(1/12) × 100 = 8% **(Choice A)**
Had potato salad = 73 (attack rate 34%)	Potato salad only	10	3	(3/10) × 100 = 30% **(Choice F)**
	Hamburgers and potato salad	25	5	(5/25) × 100 = 20% **(Choice D)**
	Hotdogs and potato salad	8	3	(3/8) × 100 = 38%
	Hamburgers, hotdogs, and	30	14	(14/30) × 100 = 47%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			vomiting	
Did not have potato salad = 27 (attack rate 11%)	Hamburgers only	15	2	(2/15) × 100 = 13% **(Choice C)**
	Hotdogs only	12	1	(1/12) × 100 = 8% **(Choice A)**
Had potato salad = 73 (attack rate 34%)	Potato salad only	10	3	(3/10) × 100 = 30% **(Choice F)**
	Hamburgers and potato salad	25	5	(5/25) × 100 = 20% **(Choice D)**
	Hotdogs and potato salad	8	3	(3/8) × 100 = 38%
	Hamburgers, hotdogs, and potato salad	30	14	(14/30) × 100 = 47% **(Choice H)**
Overall		100	28	28/100 × 100 = 28% **(Choice E)**

The food item responsible for an outbreak often (though not always) has the largest attack rate and the largest difference in attack rates between those who consumed the item and those who did not. In this example, as

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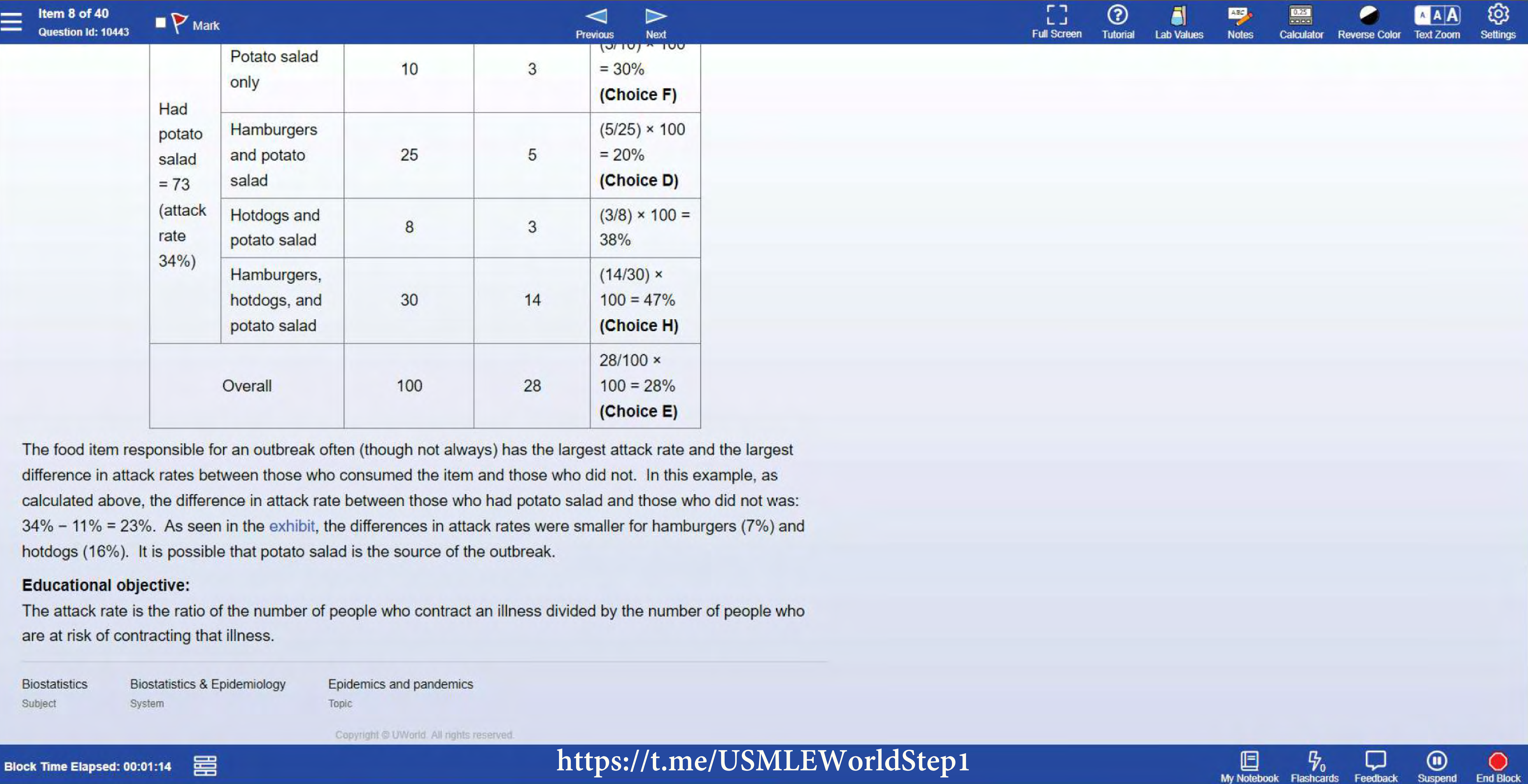
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Had potato salad = 73 (attack rate 34%)	Potato salad only	10	3	(3/10) × 100 = 30% **(Choice F)**
	Hamburgers and potato salad	25	5	(5/25) × 100 = 20% **(Choice D)**
	Hotdogs and potato salad	8	3	(3/8) × 100 = 38%
	Hamburgers, hotdogs, and potato salad	30	14	(14/30) × 100 = 47% **(Choice H)**
Overall		100	28	28/100 × 100 = 28% **(Choice E)**

The food item responsible for an outbreak often (though not always) has the largest attack rate and the largest difference in attack rates between those who consumed the item and those who did not. In this example, as calculated above, the difference in attack rate between those who had potato salad and those who did not was: 34% − 11% = 23%. As seen in the exhibit, the differences in attack rates were smaller for hamburgers (7%) and hotdogs (16%). It is possible that potato salad is the source of the outbreak.

Educational objective:

The attack rate is the ratio of the number of people who contract an illness divided by the number of people who are at risk of contracting that illness.

Biostatistics	Biostatistics & Epidemiology	Epidemics and pandemics
Subject	System	Topic

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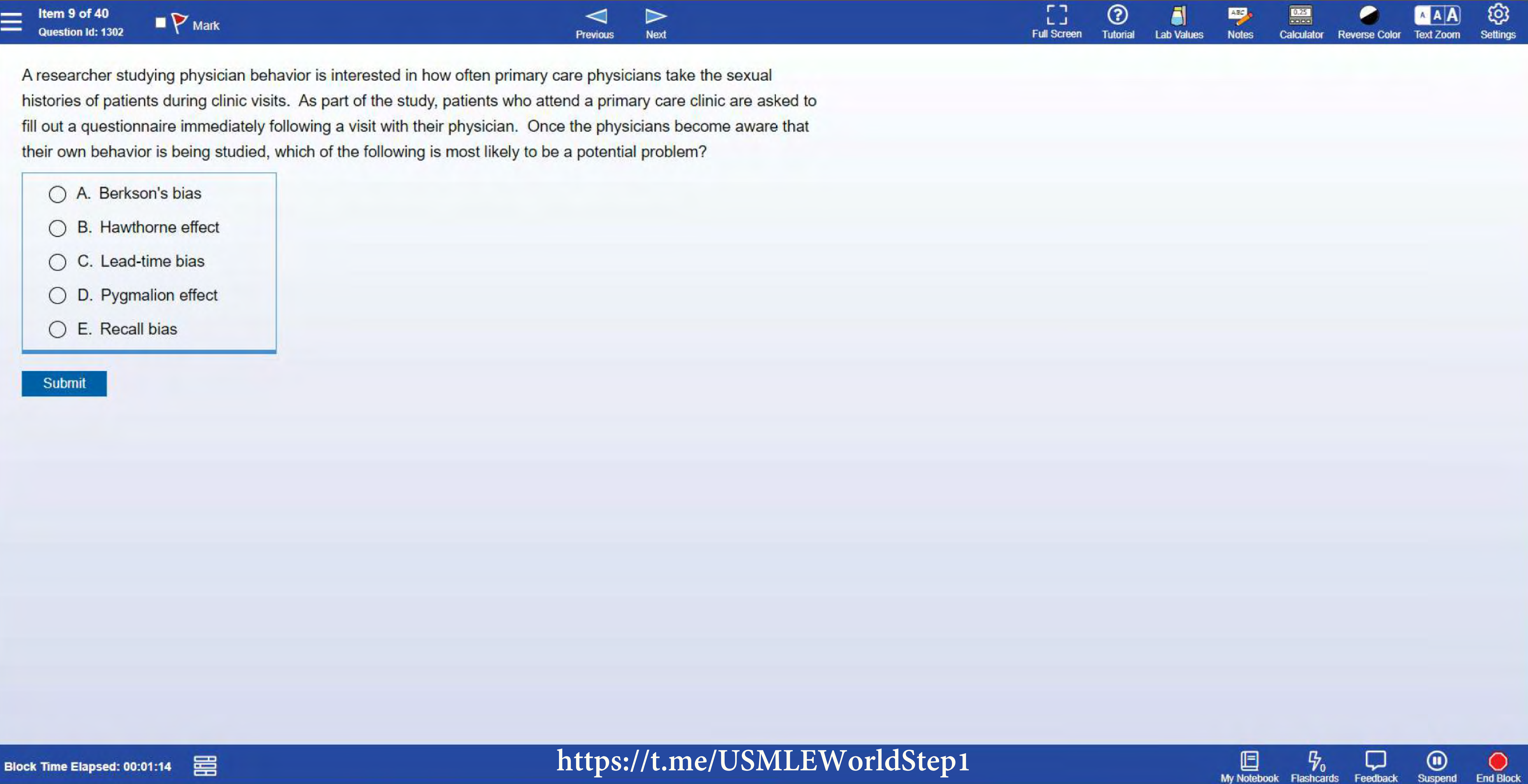
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A researcher studying physician behavior is interested in how often primary care physicians take the sexual histories of patients during clinic visits. As part of the study, patients who attend a primary care clinic are asked to fill out a questionnaire immediately following a visit with their physician. Once the physicians become aware that their own behavior is being studied, which of the following is most likely to be a potential problem?

○ A. Berkson's bias
○ B. Hawthorne effect
○ C. Lead-time bias
○ D. Pygmalion effect
○ E. Recall bias

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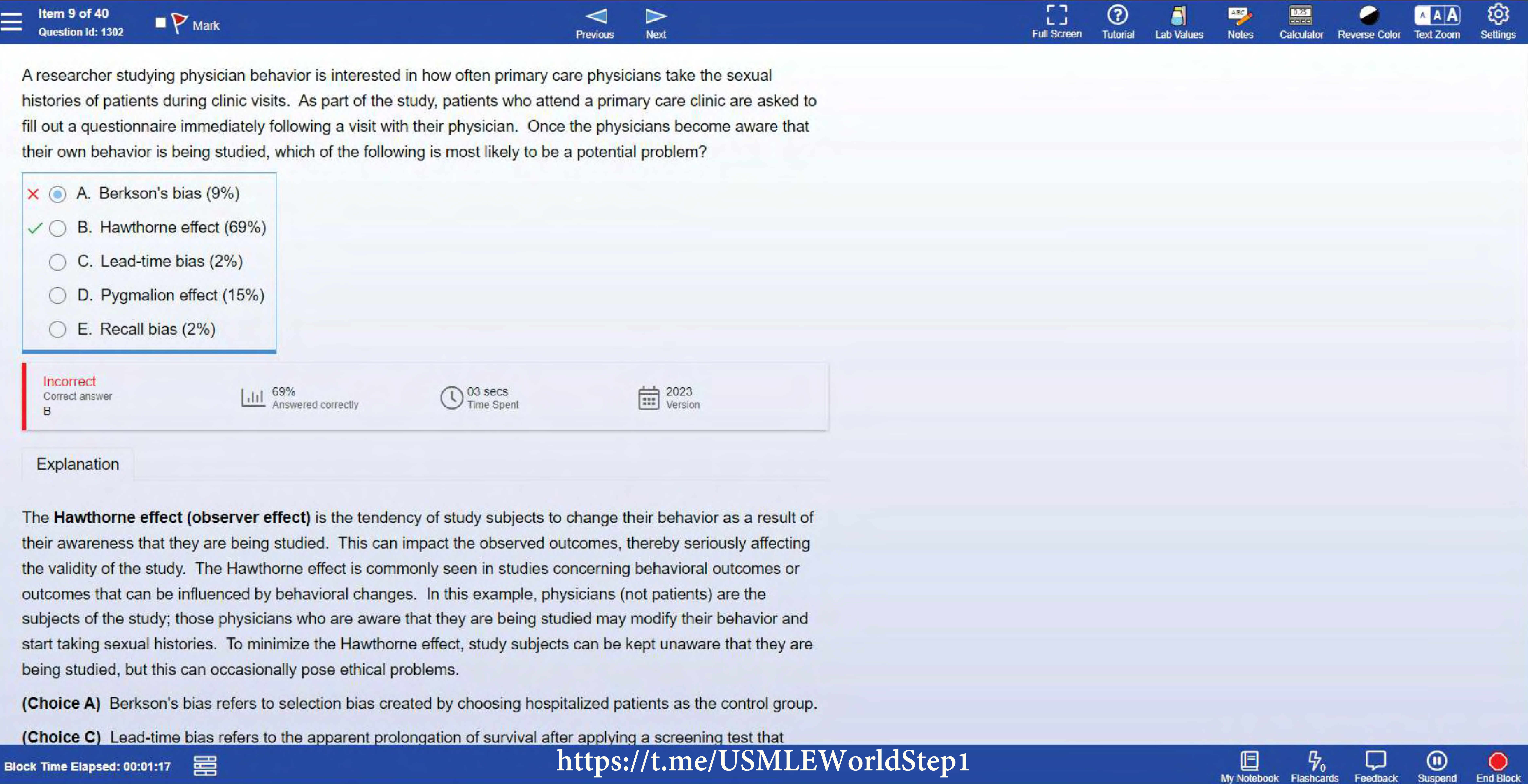
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A researcher studying physician behavior is interested in how often primary care physicians take the sexual histories of patients during clinic visits. As part of the study, patients who attend a primary care clinic are asked to fill out a questionnaire immediately following a visit with their physician. Once the physicians become aware that their own behavior is being studied, which of the following is most likely to be a potential problem?

✗ ● A. Berkson's bias (9%)
✓ ○ B. Hawthorne effect (69%)
○ C. Lead-time bias (2%)
○ D. Pygmalion effect (15%)
○ E. Recall bias (2%)

Incorrect
Correct answer
B

69%
Answered correctly

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Explanation

The **Hawthorne effect (observer effect)** is the tendency of study subjects to change their behavior as a result of their awareness that they are being studied. This can impact the observed outcomes, thereby seriously affecting the validity of the study. The Hawthorne effect is commonly seen in studies concerning behavioral outcomes or outcomes that can be influenced by behavioral changes. In this example, physicians (not patients) are the subjects of the study; those physicians who are aware that they are being studied may modify their behavior and start taking sexual histories. To minimize the Hawthorne effect, study subjects can be kept unaware that they are being studied, but this can occasionally pose ethical problems.

(Choice A) Berkson's bias refers to selection bias created by choosing hospitalized patients as the control group.

(Choice C) Lead-time bias refers to the apparent prolongation of survival after applying a screening test that

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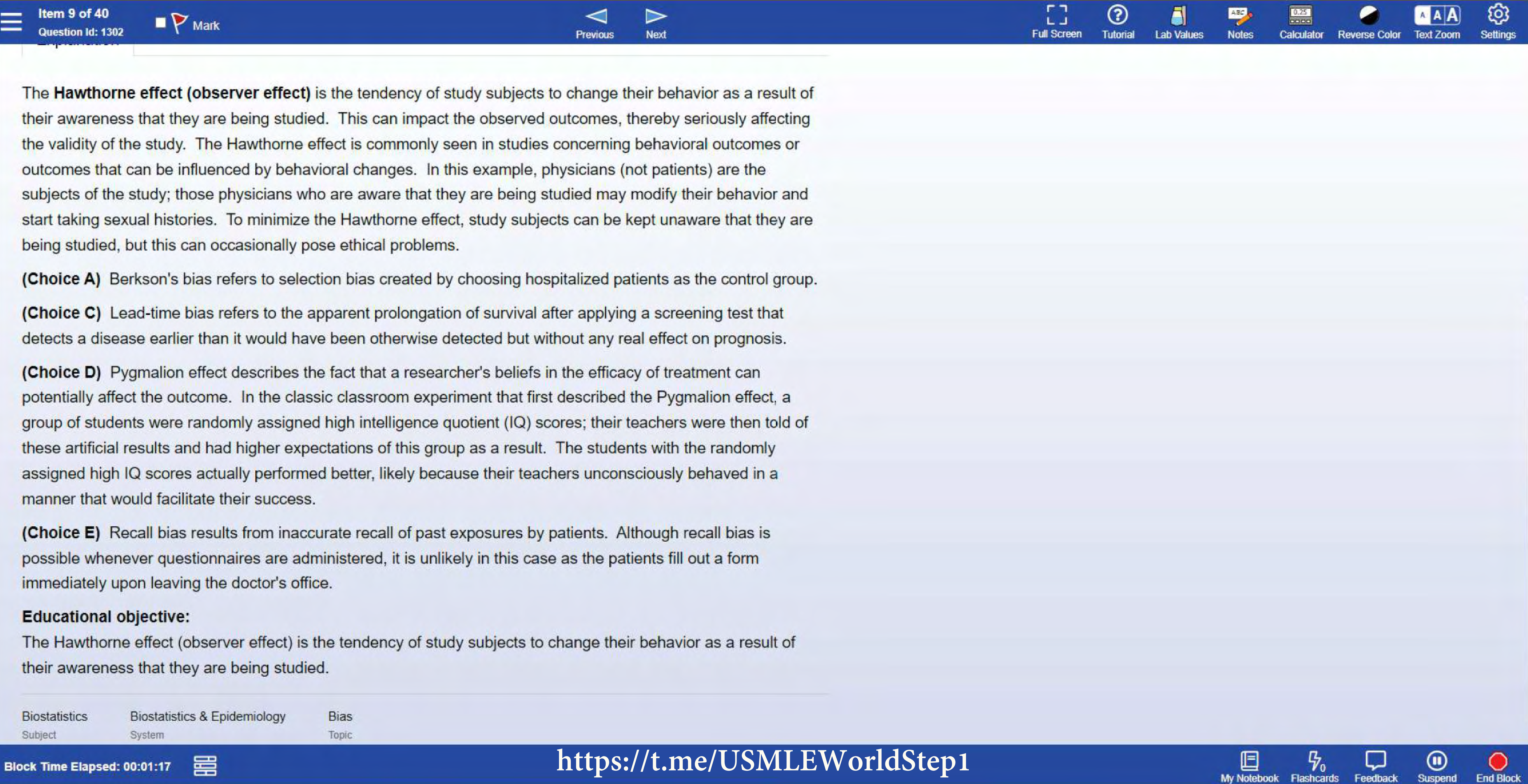


The **Hawthorne effect (observer effect)** is the tendency of study subjects to change their behavior as a result of their awareness that they are being studied. This can impact the observed outcomes, thereby seriously affecting the validity of the study. The Hawthorne effect is commonly seen in studies concerning behavioral outcomes or outcomes that can be influenced by behavioral changes. In this example, physicians (not patients) are the subjects of the study; those physicians who are aware that they are being studied may modify their behavior and start taking sexual histories. To minimize the Hawthorne effect, study subjects can be kept unaware that they are being studied, but this can occasionally pose ethical problems.

(Choice A) Berkson's bias refers to selection bias created by choosing hospitalized patients as the control group.

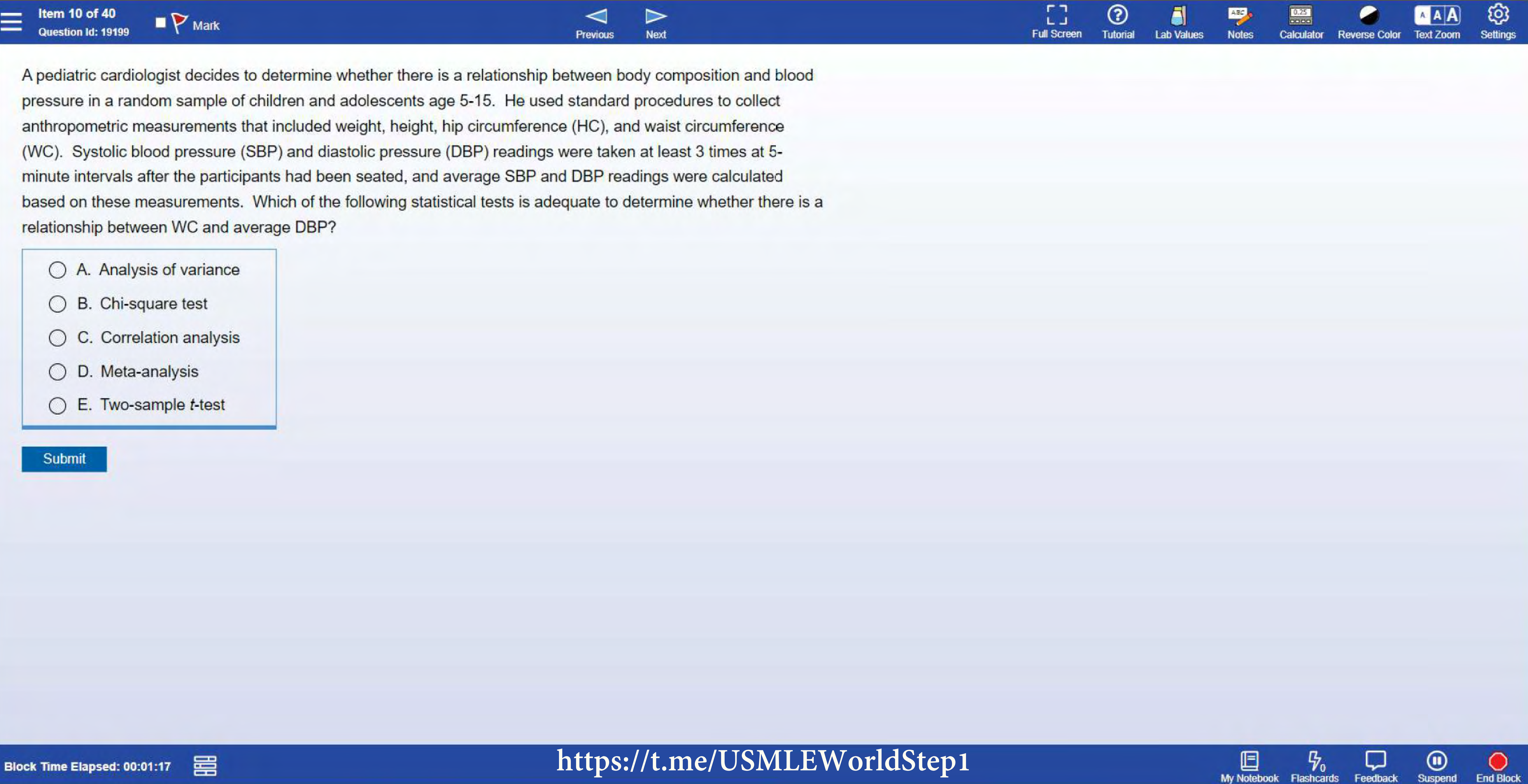
(Choice C) Lead-time bias refers to the apparent prolongation of survival after applying a screening test that detects a disease earlier than it would have been otherwise detected but without any real effect on prognosis.

(Choice D) Pygmalion effect describes the fact that a researcher's beliefs in the efficacy of treatment can potentially affect the outcome. In the classic classroom experiment that first described the Pygmalion effect, a group of students were randomly assigned high intelligence quotient (IQ) scores; their teachers were then told of these artificial results and had higher expectations of this group as a result. The students with the randomly assigned high IQ scores actually performed better, likely because their teachers unconsciously behaved in a manner that would facilitate their success.

(Choice E) Recall bias results from inaccurate recall of past exposures by patients. Although recall bias is possible whenever questionnaires are administered, it is unlikely in this case as the patients fill out a form immediately upon leaving the doctor's office.

Educational objective:
The Hawthorne effect (observer effect) is the tendency of study subjects to change their behavior as a result of their awareness that they are being studied.

Biostatistics	Biostatistics & Epidemiology	Bias
Subject	System	Topic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A pediatric cardiologist decides to determine whether there is a relationship between body composition and blood pressure in a random sample of children and adolescents age 5-15. He used standard procedures to collect anthropometric measurements that included weight, height, hip circumference (HC), and waist circumference (WC). Systolic blood pressure (SBP) and diastolic pressure (DBP) readings were taken at least 3 times at 5-minute intervals after the participants had been seated, and average SBP and DBP readings were calculated based on these measurements. Which of the following statistical tests is adequate to determine whether there is a relationship between WC and average DBP?

- ○ A. Analysis of variance
- ○ B. Chi-square test
- ○ C. Correlation analysis
- ○ D. Meta-analysis
- ○ E. Two-sample *t*-test

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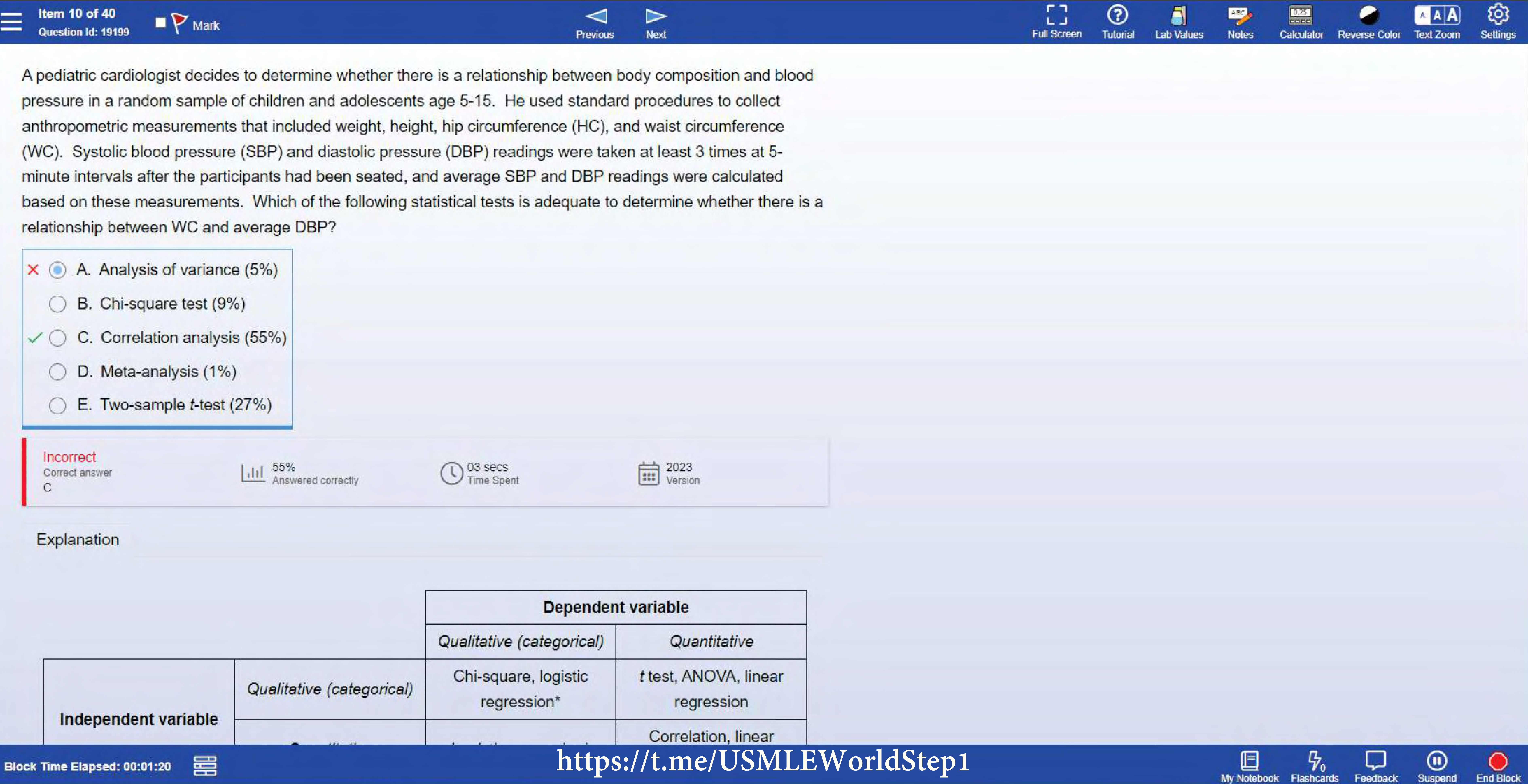
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A pediatric cardiologist decides to determine whether there is a relationship between body composition and blood pressure in a random sample of children and adolescents age 5-15. He used standard procedures to collect anthropometric measurements that included weight, height, hip circumference (HC), and waist circumference (WC). Systolic blood pressure (SBP) and diastolic pressure (DBP) readings were taken at least 3 times at 5-minute intervals after the participants had been seated, and average SBP and DBP readings were calculated based on these measurements. Which of the following statistical tests is adequate to determine whether there is a relationship between WC and average DBP?

✗ ● A. Analysis of variance (5%)
○ B. Chi-square test (9%)
✓ ○ C. Correlation analysis (55%)
○ D. Meta-analysis (1%)
○ E. Two-sample *t*-test (27%)

Incorrect
Correct answer
C

55%
Answered correctly

03 secs
Time Spent

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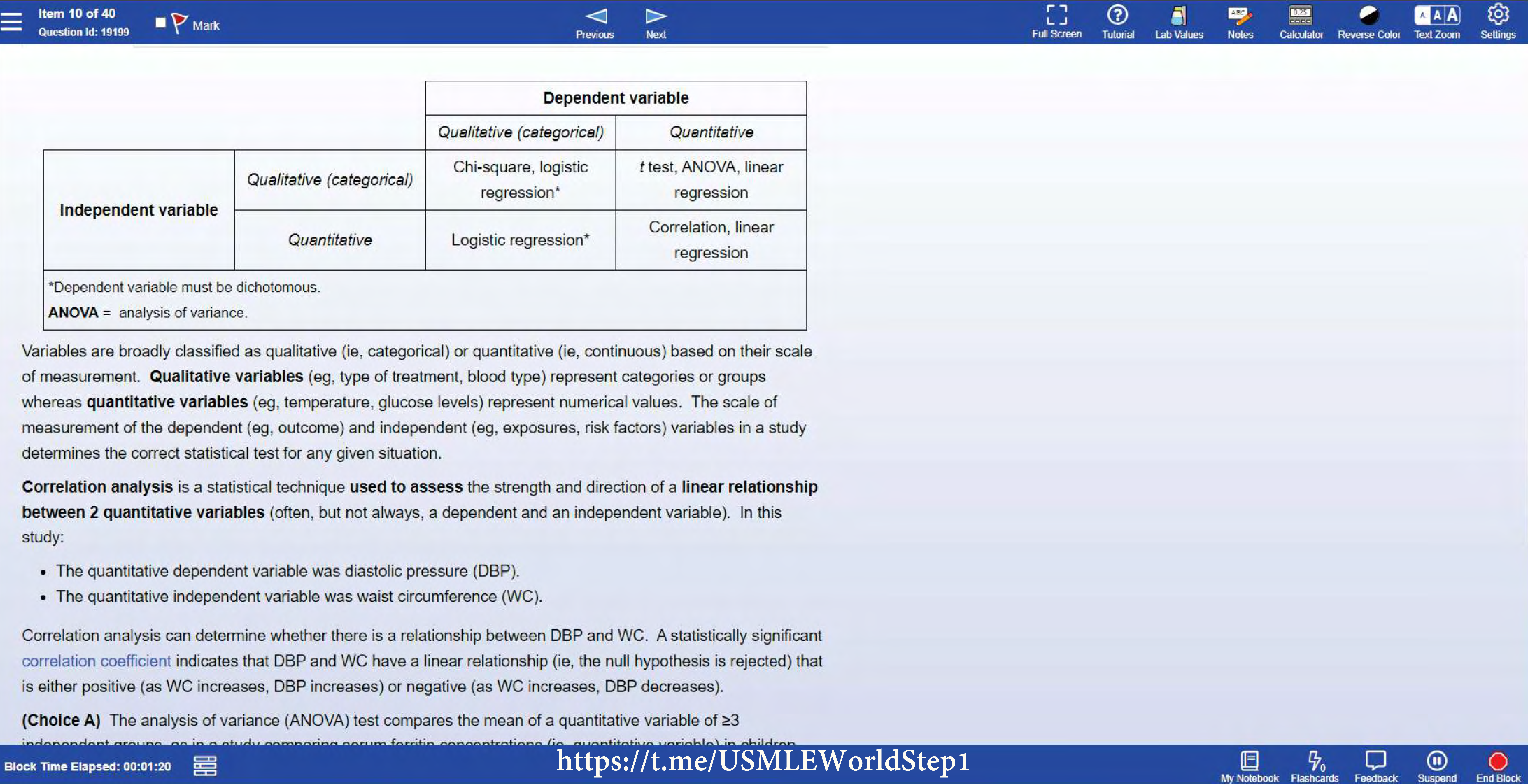
Explanation

		Dependent variable	
		Qualitative (categorical)	*Quantitative*
Independent variable	*Qualitative (categorical)*	Chi-square, logistic regression*	*t* test, ANOVA, linear regression
			Correlation, linear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		Dependent variable	
		Qualitative (categorical)	*Quantitative*
Independent variable	*Qualitative (categorical)*	Chi-square, logistic regression*	*t* test, ANOVA, linear regression
	Quantitative	Logistic regression*	Correlation, linear regression

*Dependent variable must be dichotomous.

ANOVA = analysis of variance.

Variables are broadly classified as qualitative (ie, categorical) or quantitative (ie, continuous) based on their scale of measurement. **Qualitative variables** (eg, type of treatment, blood type) represent categories or groups whereas **quantitative variables** (eg, temperature, glucose levels) represent numerical values. The scale of measurement of the dependent (eg, outcome) and independent (eg, exposures, risk factors) variables in a study determines the correct statistical test for any given situation.

Correlation analysis is a statistical technique **used to assess** the strength and direction of a **linear relationship between 2 quantitative variables** (often, but not always, a dependent and an independent variable). In this study:

- The quantitative dependent variable was diastolic pressure (DBP).
- The quantitative independent variable was waist circumference (WC).

Correlation analysis can determine whether there is a relationship between DBP and WC. A statistically significant correlation coefficient indicates that DBP and WC have a linear relationship (ie, the null hypothesis is rejected) that is either positive (as WC increases, DBP increases) or negative (as WC increases, DBP decreases).

(Choice A) The analysis of variance (ANOVA) test compares the mean of a quantitative variable of ≥3 independent groups, as in a study comparing serum ferritin concentrations (ie, quantitative variable) in children

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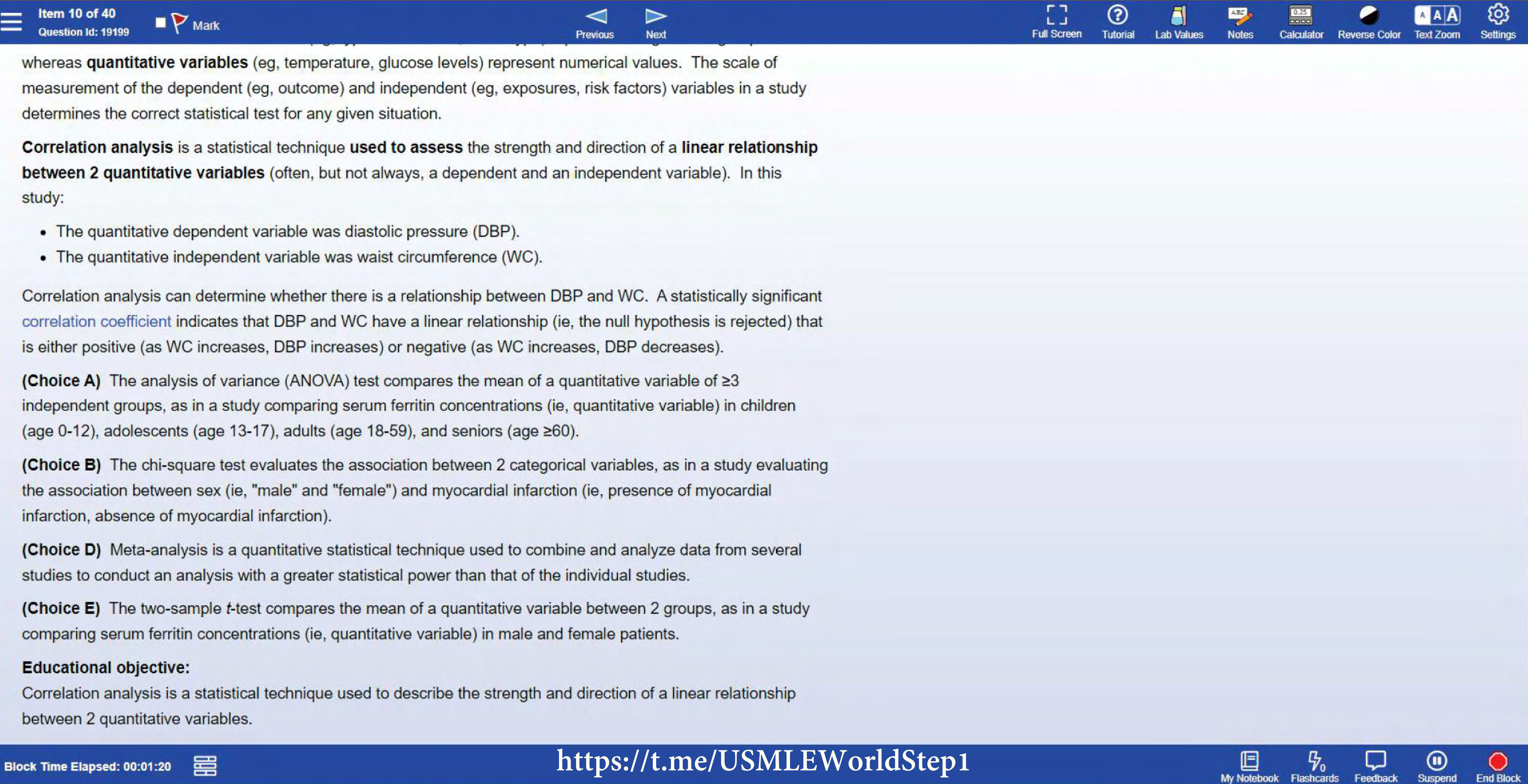


whereas **quantitative variables** (eg, temperature, glucose levels) represent numerical values. The scale of measurement of the dependent (eg, outcome) and independent (eg, exposures, risk factors) variables in a study determines the correct statistical test for any given situation.

Correlation analysis is a statistical technique **used to assess** the strength and direction of a **linear relationship between 2 quantitative variables** (often, but not always, a dependent and an independent variable). In this study:

- The quantitative dependent variable was diastolic pressure (DBP).
- The quantitative independent variable was waist circumference (WC).

Correlation analysis can determine whether there is a relationship between DBP and WC. A statistically significant correlation coefficient indicates that DBP and WC have a linear relationship (ie, the null hypothesis is rejected) that is either positive (as WC increases, DBP increases) or negative (as WC increases, DBP decreases).

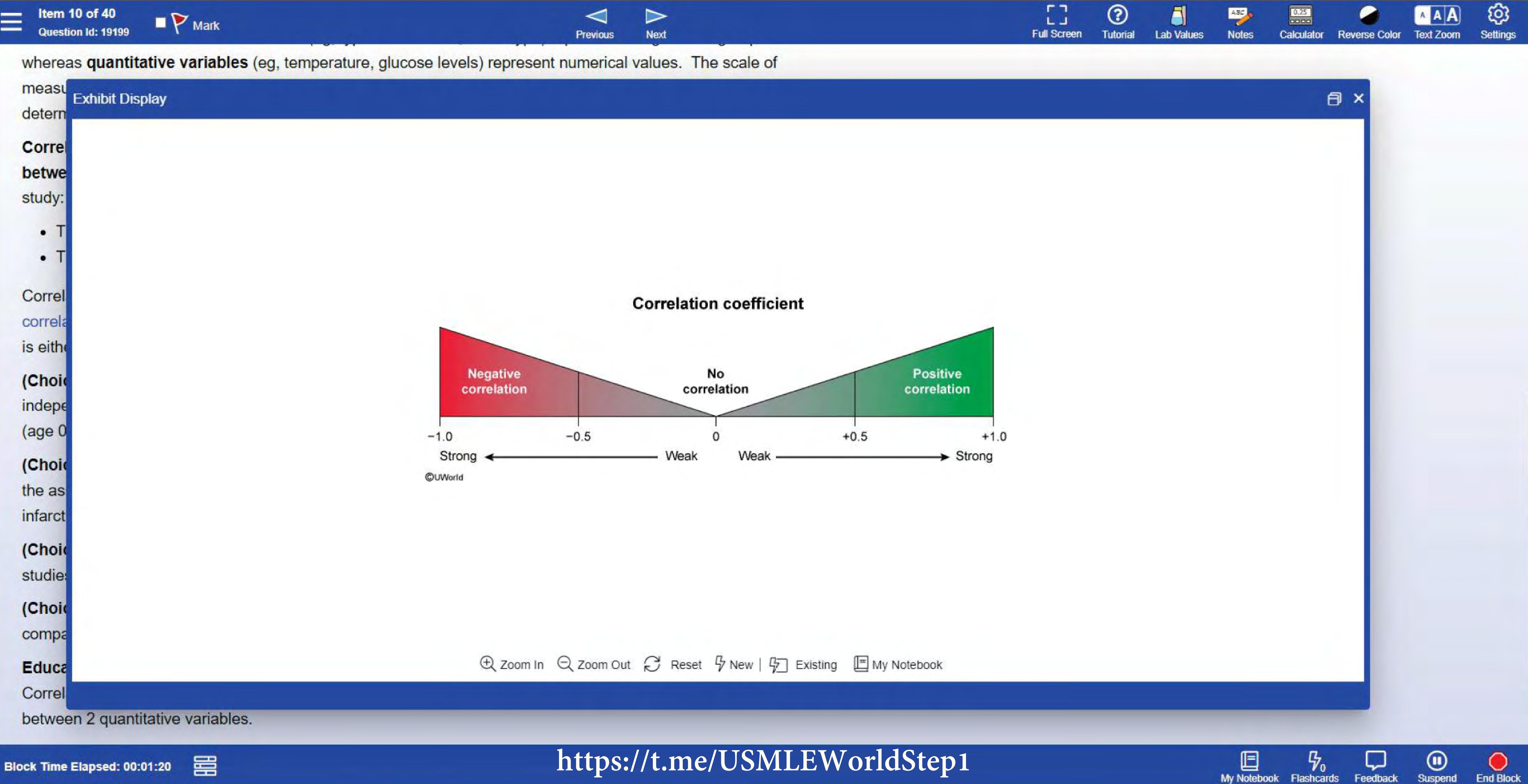
(Choice A) The analysis of variance (ANOVA) test compares the mean of a quantitative variable of ≥3 independent groups, as in a study comparing serum ferritin concentrations (ie, quantitative variable) in children (age 0-12), adolescents (age 13-17), adults (age 18-59), and seniors (age ≥60).

(Choice B) The chi-square test evaluates the association between 2 categorical variables, as in a study evaluating the association between sex (ie, "male" and "female") and myocardial infarction (ie, presence of myocardial infarction, absence of myocardial infarction).

(Choice D) Meta-analysis is a quantitative statistical technique used to combine and analyze data from several studies to conduct an analysis with a greater statistical power than that of the individual studies.

(Choice E) The two-sample *t*-test compares the mean of a quantitative variable between 2 groups, as in a study comparing serum ferritin concentrations (ie, quantitative variable) in male and female patients.

Educational objective:
Correlation analysis is a statistical technique used to describe the strength and direction of a linear relationship between 2 quantitative variables.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Correlation coefficient
Negative correlation
No correlation
Positive correlation
−1.0
−0.5
0
+0.5
+1.0
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Weak
Weak
Strong
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whereas **quantitative variables** (eg, temperature, glucose levels) represent numerical values. The scale of

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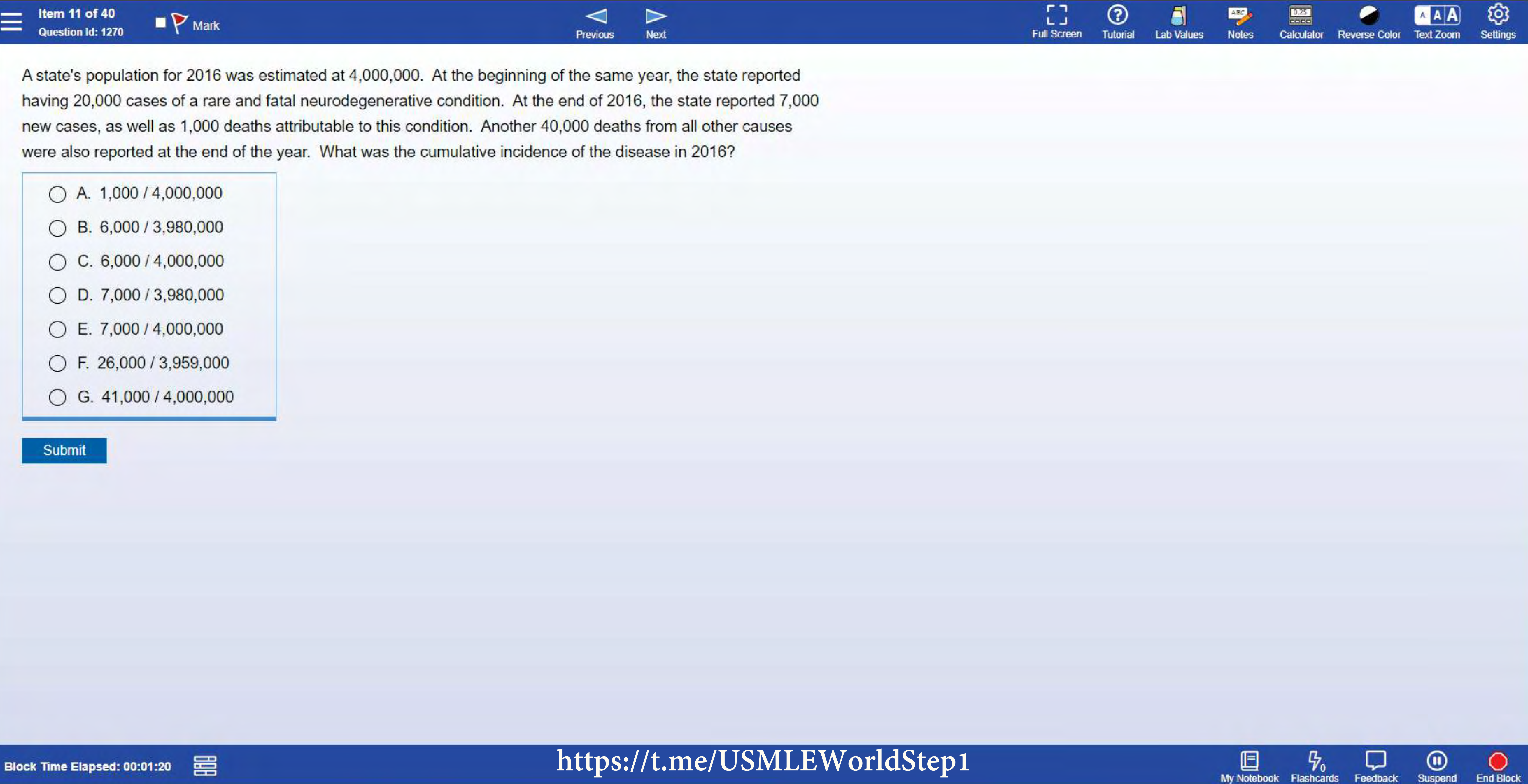
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Question Id: 1270

A state's population for 2016 was estimated at 4,000,000. At the beginning of the same year, the state reported having 20,000 cases of a rare and fatal neurodegenerative condition. At the end of 2016, the state reported 7,000 new cases, as well as 1,000 deaths attributable to this condition. Another 40,000 deaths from all other causes were also reported at the end of the year. What was the cumulative incidence of the disease in 2016?

○ A. 1,000 / 4,000,000
○ B. 6,000 / 3,980,000
○ C. 6,000 / 4,000,000
○ D. 7,000 / 3,980,000
○ E. 7,000 / 4,000,000
○ F. 26,000 / 3,959,000
○ G. 41,000 / 4,000,000

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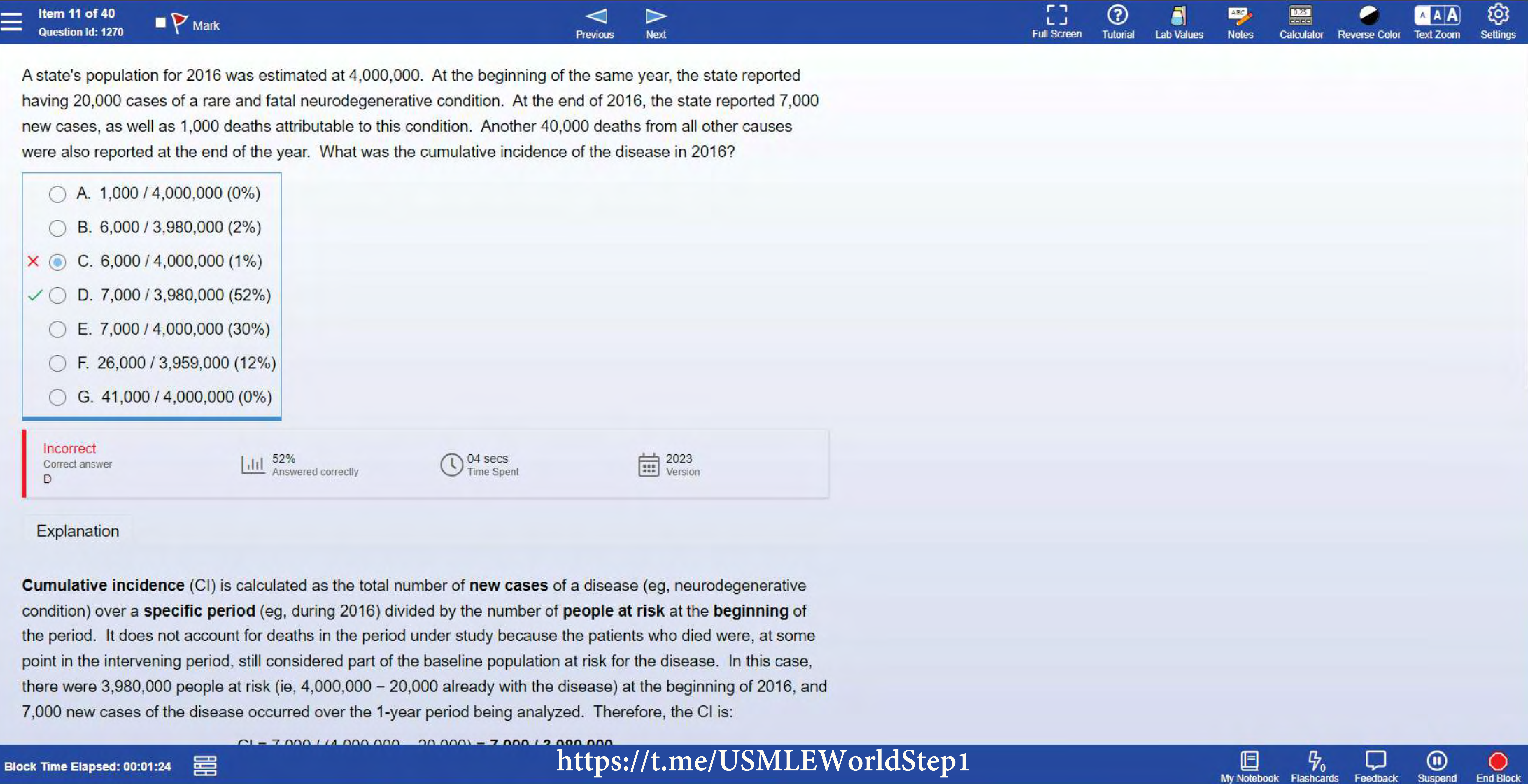
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A state's population for 2016 was estimated at 4,000,000. At the beginning of the same year, the state reported having 20,000 cases of a rare and fatal neurodegenerative condition. At the end of 2016, the state reported 7,000 new cases, as well as 1,000 deaths attributable to this condition. Another 40,000 deaths from all other causes were also reported at the end of the year. What was the cumulative incidence of the disease in 2016?

- ○ A. 1,000 / 4,000,000 (0%)
- ○ B. 6,000 / 3,980,000 (2%)
- ✗ ● C. 6,000 / 4,000,000 (1%)
- ✓ ○ D. 7,000 / 3,980,000 (52%)
- ○ E. 7,000 / 4,000,000 (30%)
- ○ F. 26,000 / 3,959,000 (12%)
- ○ G. 41,000 / 4,000,000 (0%)

Incorrect
Correct answer
D

52%
Answered correctly

04 secs
Time Spent

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Version

Explanation

Cumulative incidence (CI) is calculated as the total number of **new cases** of a disease (eg, neurodegenerative condition) over a **specific period** (eg, during 2016) divided by the number of **people at risk** at the **beginning** of the period. It does not account for deaths in the period under study because the patients who died were, at some point in the intervening period, still considered part of the baseline population at risk for the disease. In this case, there were 3,980,000 people at risk (ie, 4,000,000 − 20,000 already with the disease) at the beginning of 2016, and 7,000 new cases of the disease occurred over the 1-year period being analyzed. Therefore, the CI is:

CI = 7,000 / (4,000,000 − 20,000) = **7,000 / 3,980,000**

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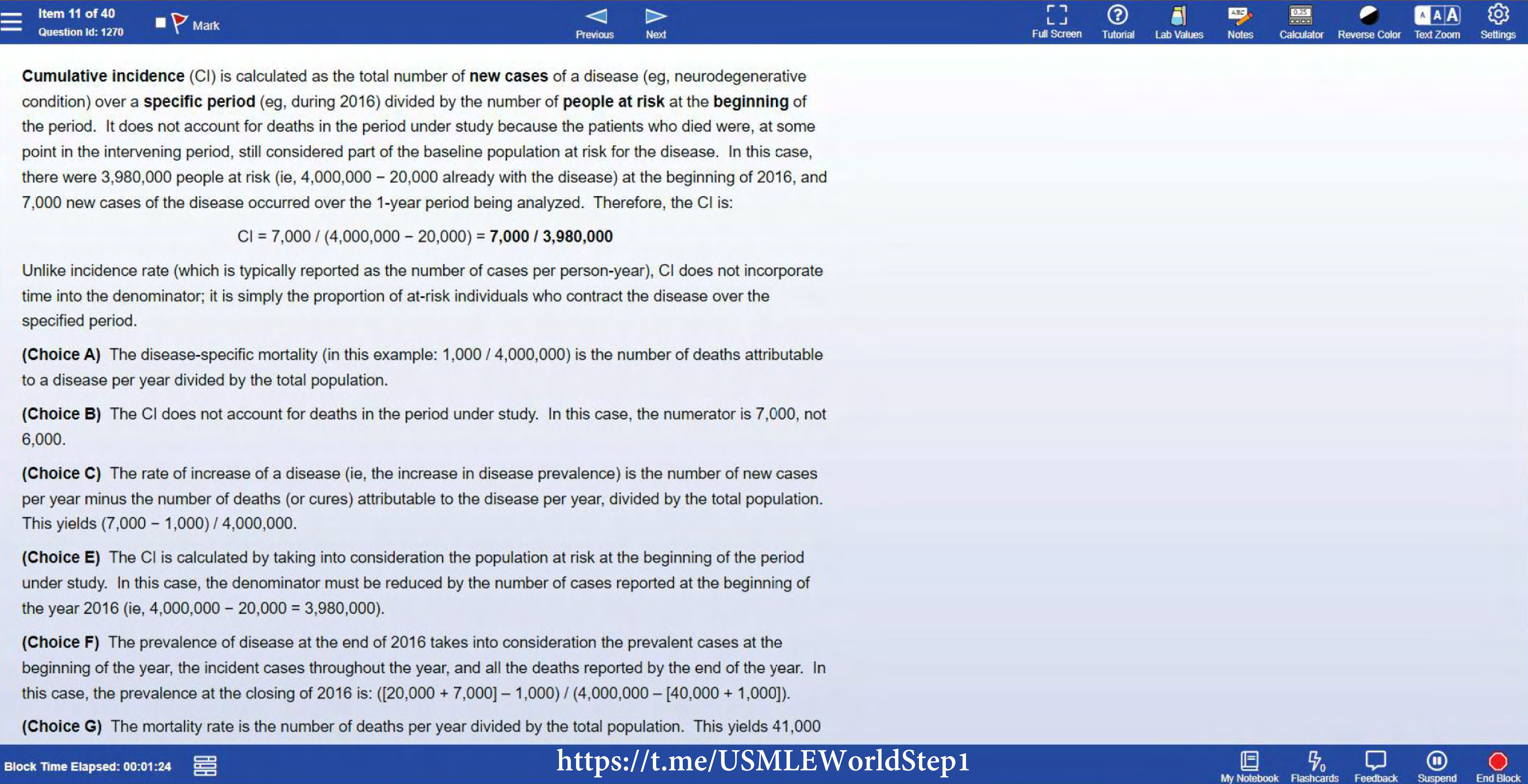

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CI = 7,000 / (4,000,000 – 20,000) = **7,000 / 3,980,000**

Unlike incidence rate (which is typically reported as the number of cases per person-year), CI does not incorporate time into the denominator; it is simply the proportion of at-risk individuals who contract the disease over the specified period.

(Choice A) The disease-specific mortality (in this example: 1,000 / 4,000,000) is the number of deaths attributable to a disease per year divided by the total population.

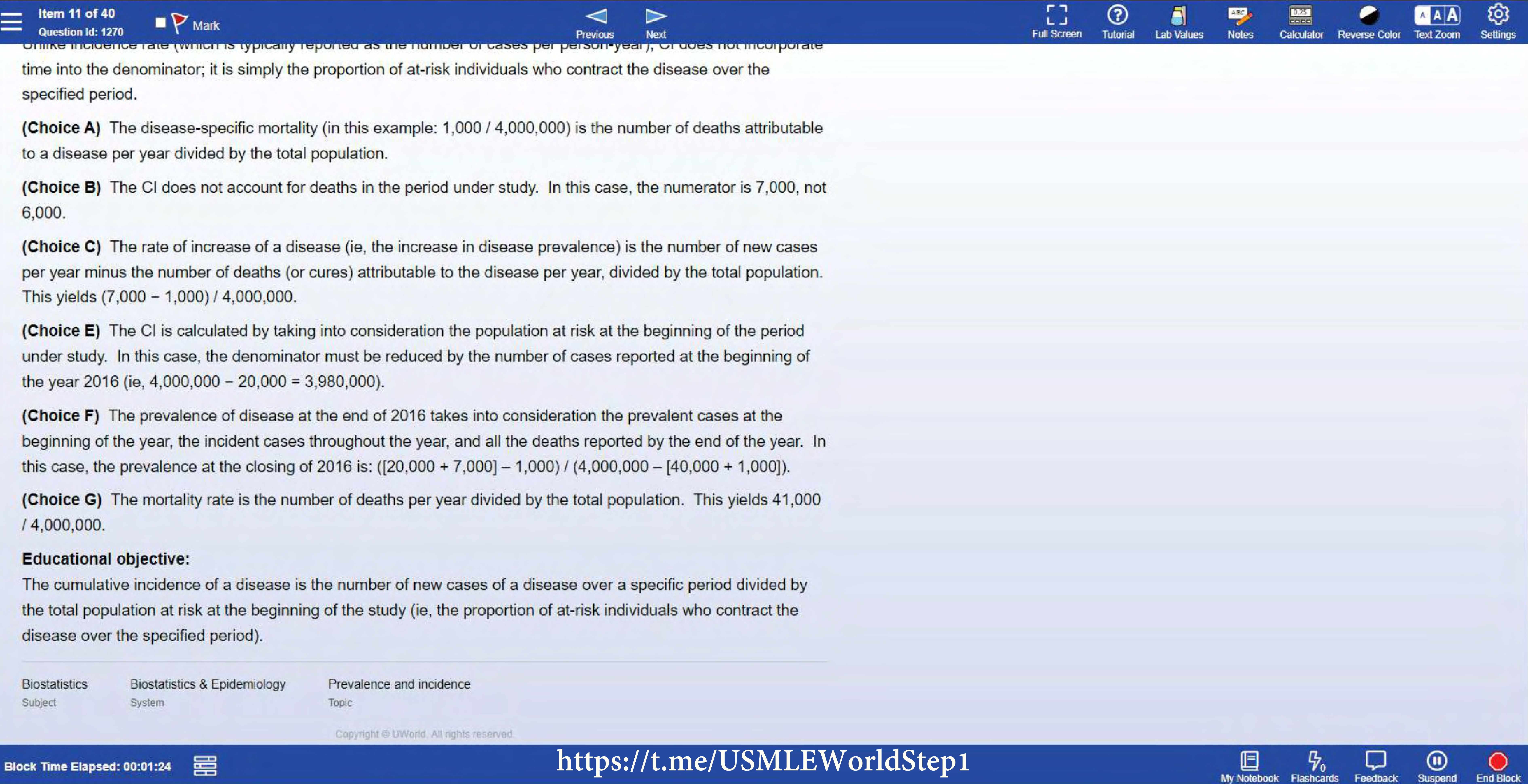
(Choice B) The CI does not account for deaths in the period under study. In this case, the numerator is 7,000, not 6,000.

(Choice C) The rate of increase of a disease (ie, the increase in disease prevalence) is the number of new cases per year minus the number of deaths (or cures) attributable to the disease per year, divided by the total population. This yields (7,000 – 1,000) / 4,000,000.

(Choice E) The CI is calculated by taking into consideration the population at risk at the beginning of the period under study. In this case, the denominator must be reduced by the number of cases reported at the beginning of the year 2016 (ie, 4,000,000 – 20,000 = 3,980,000).

(Choice F) The prevalence of disease at the end of 2016 takes into consideration the prevalent cases at the beginning of the year, the incident cases throughout the year, and all the deaths reported by the end of the year. In this case, the prevalence at the closing of 2016 is: ([20,000 + 7,000] – 1,000) / (4,000,000 – [40,000 + 1,000]).

(Choice G) The mortality rate is the number of deaths per year divided by the total population. This yields 41,000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(Choice A) The disease-specific mortality (in this example: 1,000 / 4,000,000) is the number of deaths attributable to a disease per year divided by the total population.

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(Choice E) The CI is calculated by taking into consideration the population at risk at the beginning of the period under study. In this case, the denominator must be reduced by the number of cases reported at the beginning of the year 2016 (ie, 4,000,000 − 20,000 = 3,980,000).

(Choice F) The prevalence of disease at the end of 2016 takes into consideration the prevalent cases at the beginning of the year, the incident cases throughout the year, and all the deaths reported by the end of the year. In this case, the prevalence at the closing of 2016 is: ([20,000 + 7,000] – 1,000) / (4,000,000 – [40,000 + 1,000]).

(Choice G) The mortality rate is the number of deaths per year divided by the total population. This yields 41,000 / 4,000,000.

Educational objective:

The cumulative incidence of a disease is the number of new cases of a disease over a specific period divided by the total population at risk at the beginning of the study (ie, the proportion of at-risk individuals who contract the disease over the specified period).

Biostatistics	Biostatistics & Epidemiology	Prevalence and incidence
Subject	System	Topic

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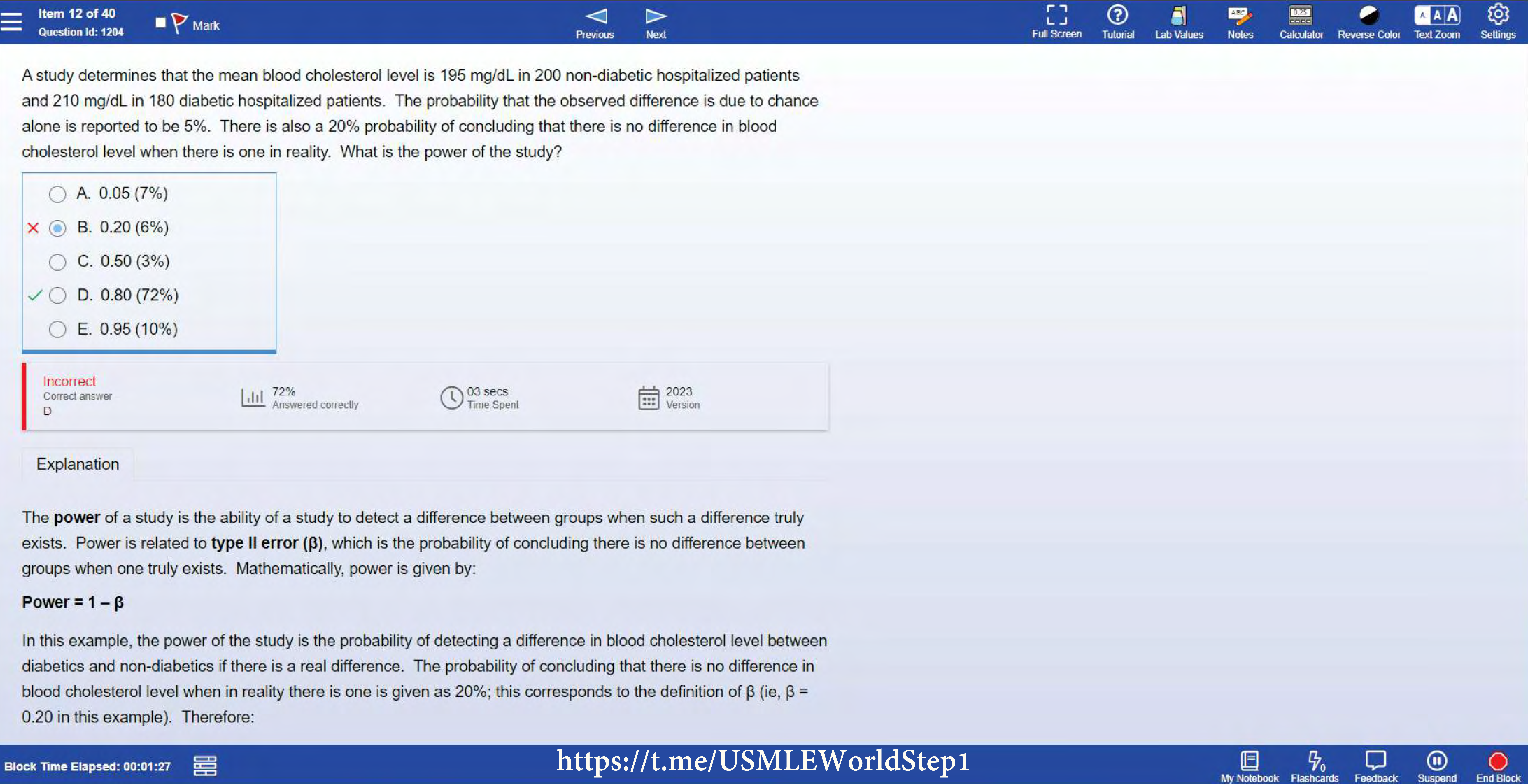
A study determines that the mean blood cholesterol level is 195 mg/dL in 200 non-diabetic hospitalized patients and 210 mg/dL in 180 diabetic hospitalized patients. The probability that the observed difference is due to chance alone is reported to be 5%. There is also a 20% probability of concluding that there is no difference in blood cholesterol level when there is one in reality. What is the power of the study?

○ A. 0.05
○ B. 0.20
○ C. 0.50
○ D. 0.80
○ E. 0.95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- ○ A. 0.05 (7%)
- ✗ ● B. 0.20 (6%)
- ○ C. 0.50 (3%)
- ✓ ○ D. 0.80 (72%)
- ○ E. 0.95 (10%)

Incorrect
Correct answer
D

72%
Answered correctly

03 secs
Time Spent

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Explanation

The **power** of a study is the ability of a study to detect a difference between groups when such a difference truly exists. Power is related to **type II error (β)**, which is the probability of concluding there is no difference between groups when one truly exists. Mathematically, power is given by:

Power = 1 – β

In this example, the power of the study is the probability of detecting a difference in blood cholesterol level between diabetics and non-diabetics if there is a real difference. The probability of concluding that there is no difference in blood cholesterol level when in reality there is one is given as 20%; this corresponds to the definition of β (ie, β = 0.20 in this example). Therefore:

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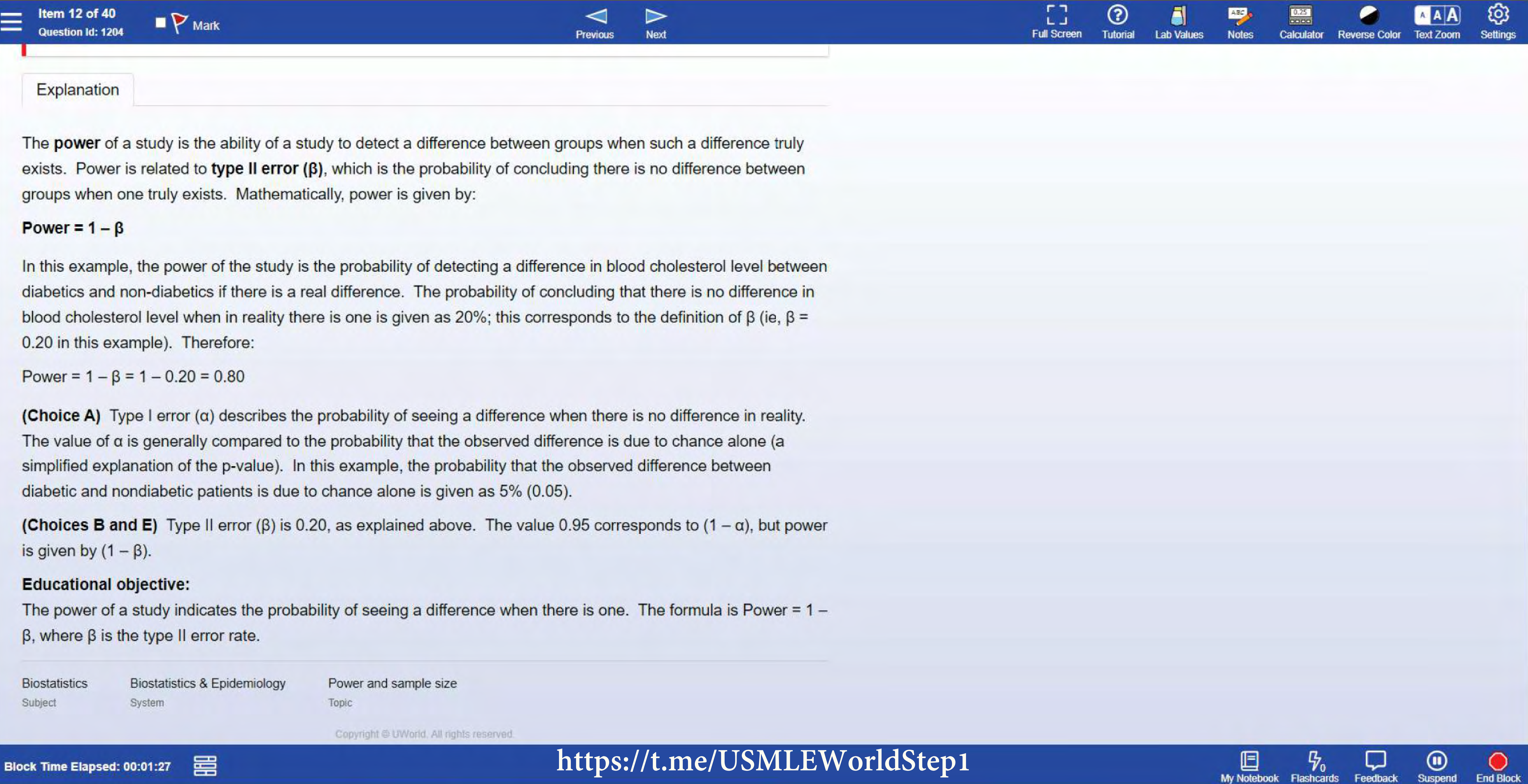
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Explanation
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Power = 1 – β

In this example, the power of the study is the probability of detecting a difference in blood cholesterol level between diabetics and non-diabetics if there is a real difference. The probability of concluding that there is no difference in blood cholesterol level when in reality there is one is given as 20%; this corresponds to the definition of β (ie, β = 0.20 in this example). Therefore:

Power = 1 – β = 1 – 0.20 = 0.80

(Choice A) Type I error (α) describes the probability of seeing a difference when there is no difference in reality. The value of α is generally compared to the probability that the observed difference is due to chance alone (a simplified explanation of the p-value). In this example, the probability that the observed difference between diabetic and nondiabetic patients is due to chance alone is given as 5% (0.05).

(Choices B and E) Type II error (β) is 0.20, as explained above. The value 0.95 corresponds to (1 – α), but power is given by (1 – β).

Educational objective:
The power of a study indicates the probability of seeing a difference when there is one. The formula is Power = 1 – β, where β is the type II error rate.

Biostatistics	Biostatistics & Epidemiology	Power and sample size
Subject	System	Topic

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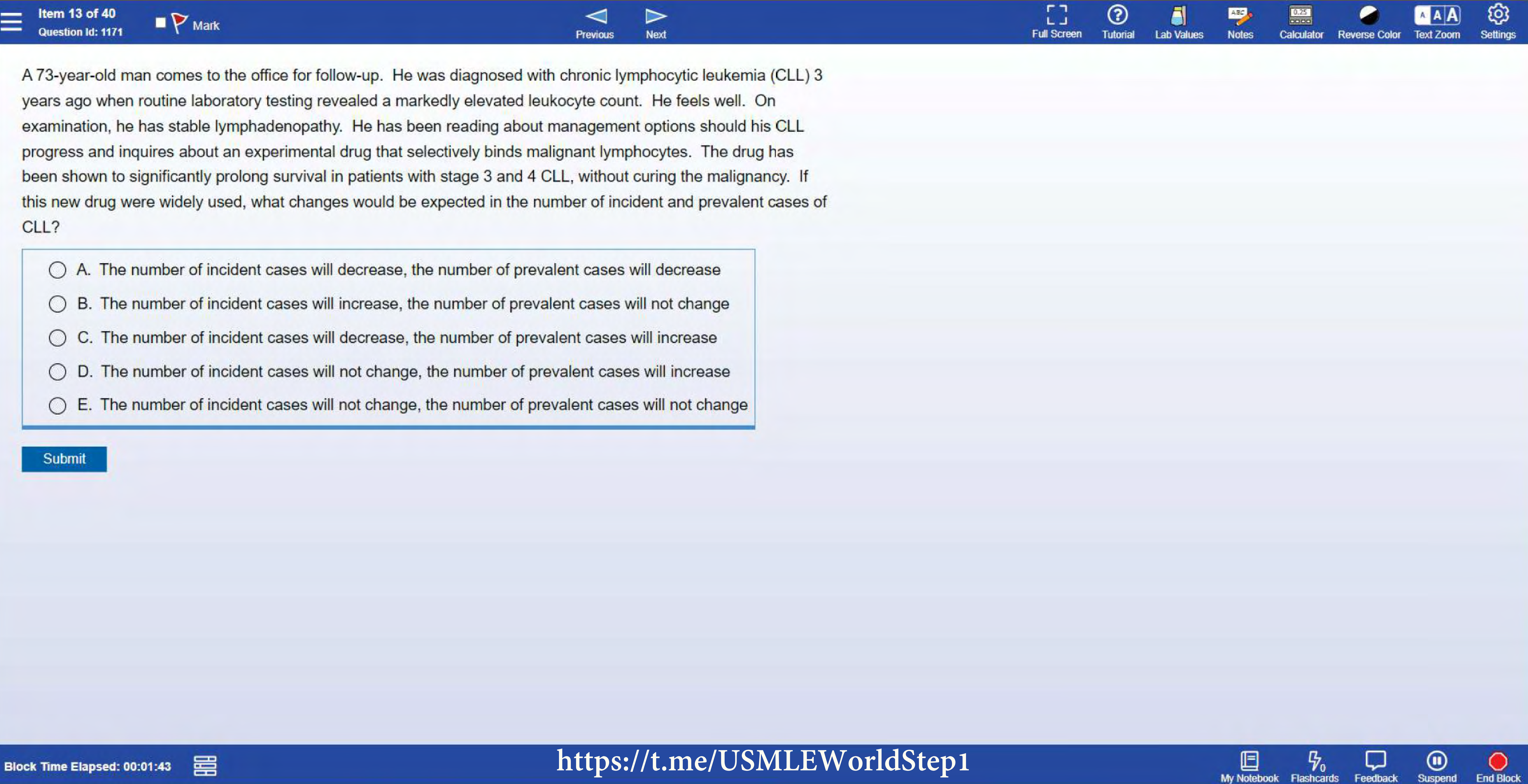
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A 73-year-old man comes to the office for follow-up. He was diagnosed with chronic lymphocytic leukemia (CLL) 3 years ago when routine laboratory testing revealed a markedly elevated leukocyte count. He feels well. On examination, he has stable lymphadenopathy. He has been reading about management options should his CLL progress and inquires about an experimental drug that selectively binds malignant lymphocytes. The drug has been shown to significantly prolong survival in patients with stage 3 and 4 CLL, without curing the malignancy. If this new drug were widely used, what changes would be expected in the number of incident and prevalent cases of CLL?

○ A. The number of incident cases will decrease, the number of prevalent cases will decrease

○ B. The number of incident cases will increase, the number of prevalent cases will not change

○ C. The number of incident cases will decrease, the number of prevalent cases will increase

○ D. The number of incident cases will not change, the number of prevalent cases will increase

○ E. The number of incident cases will not change, the number of prevalent cases will not change

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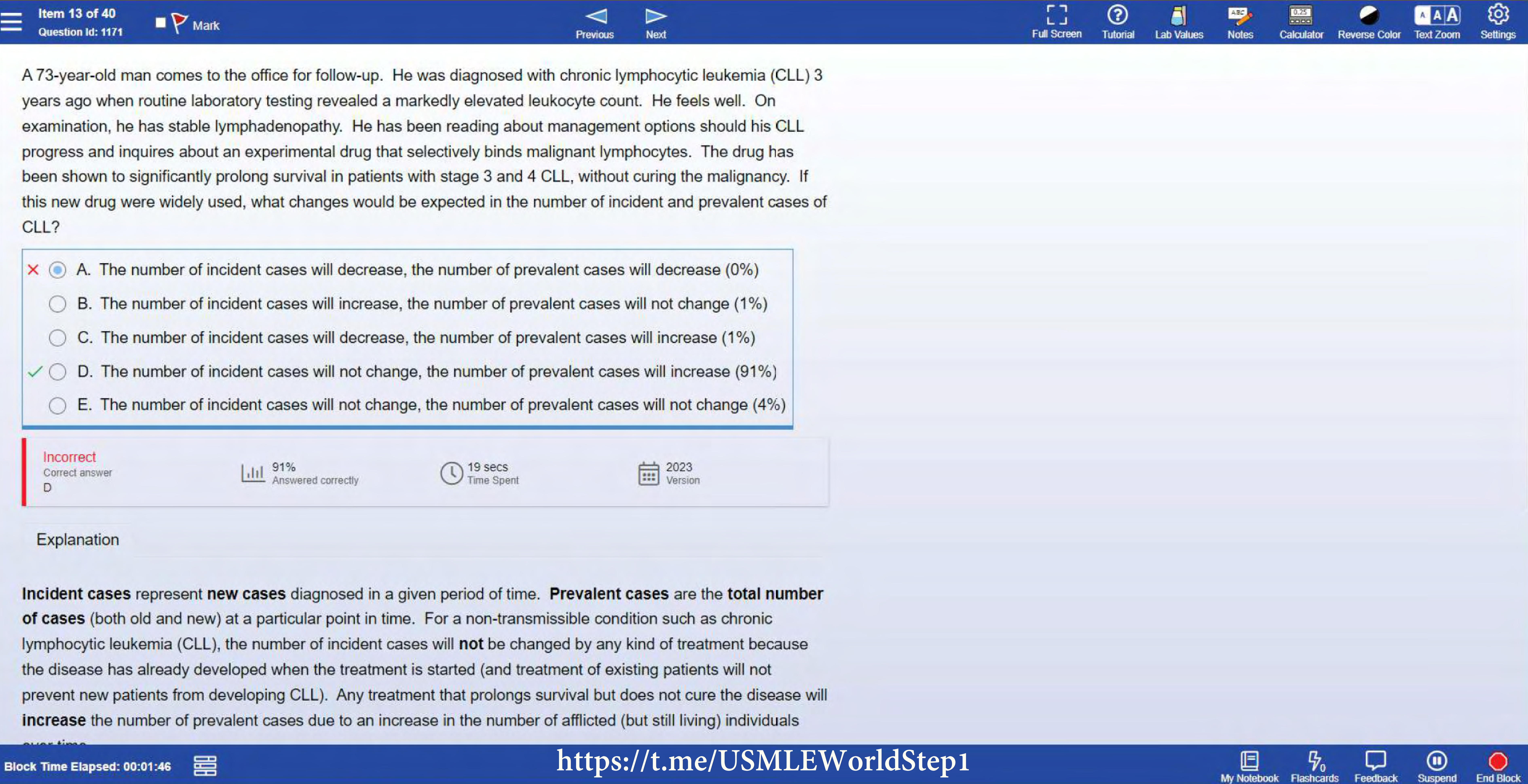
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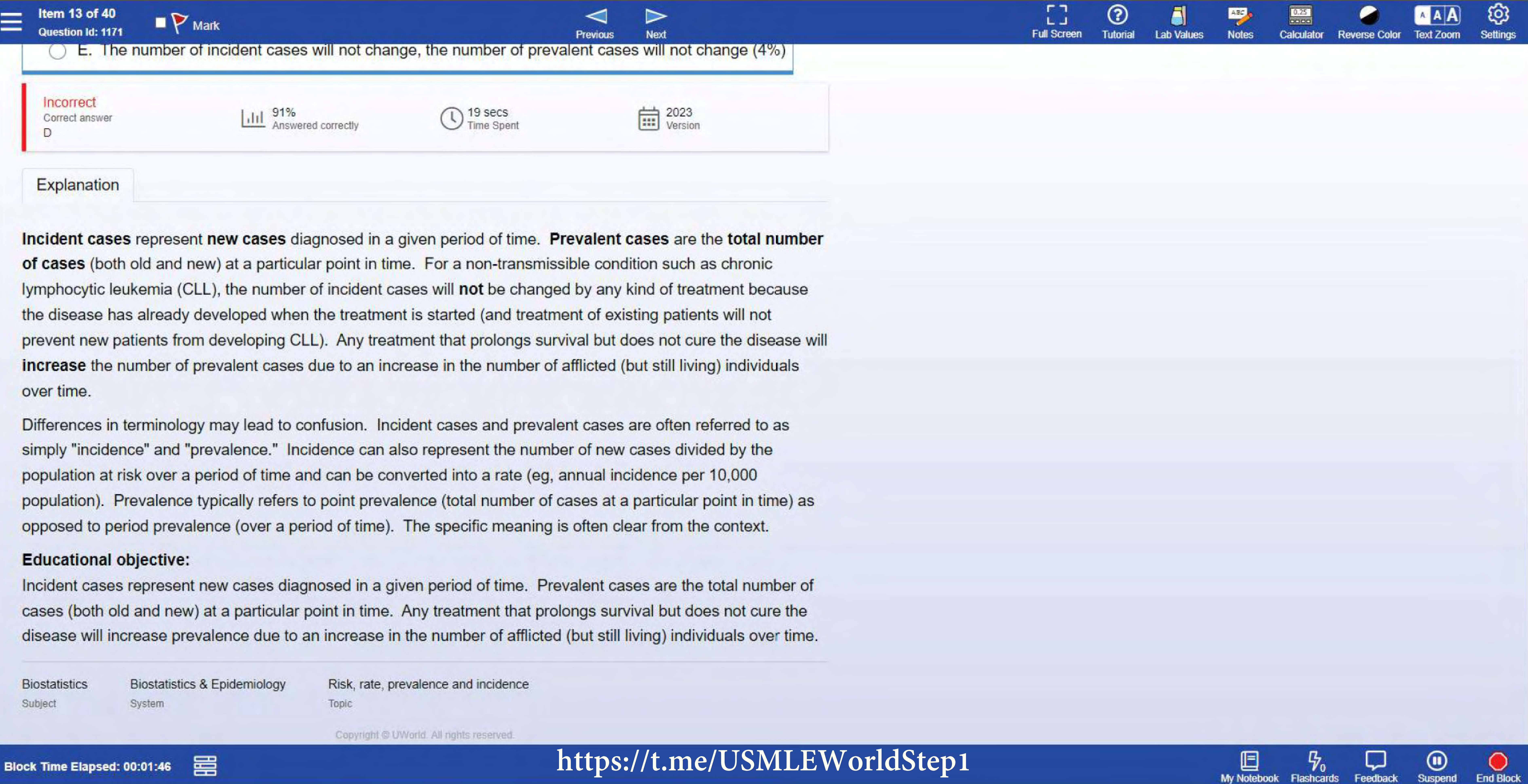
A 73-year-old man comes to the office for follow-up. He was diagnosed with chronic lymphocytic leukemia (CLL) 3 years ago when routine laboratory testing revealed a markedly elevated leukocyte count. He feels well. On examination, he has stable lymphadenopathy. He has been reading about management options should his CLL progress and inquires about an experimental drug that selectively binds malignant lymphocytes. The drug has been shown to significantly prolong survival in patients with stage 3 and 4 CLL, without curing the malignancy. If this new drug were widely used, what changes would be expected in the number of incident and prevalent cases of CLL?

- ✗ ● A. The number of incident cases will decrease, the number of prevalent cases will decrease (0%)
- ○ B. The number of incident cases will increase, the number of prevalent cases will not change (1%)
- ○ C. The number of incident cases will decrease, the number of prevalent cases will increase (1%)
- ✓ ○ D. The number of incident cases will not change, the number of prevalent cases will increase (91%)
- ○ E. The number of incident cases will not change, the number of prevalent cases will not change (4%)

Incorrect Correct answer D	91% Answered correctly	19 secs Time Spent	2023 Version

Explanation

Incident cases represent **new cases** diagnosed in a given period of time. **Prevalent cases** are the **total number of cases** (both old and new) at a particular point in time. For a non-transmissible condition such as chronic lymphocytic leukemia (CLL), the number of incident cases will **not** be changed by any kind of treatment because the disease has already developed when the treatment is started (and treatment of existing patients will not prevent new patients from developing CLL). Any treatment that prolongs survival but does not cure the disease will **increase** the number of prevalent cases due to an increase in the number of afflicted (but still living) individuals over time.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○ E. The number of incident cases will not change, the number of prevalent cases will not change (4%)

Incorrect
Correct answer
D

91%
Answered correctly

19 secs
Time Spent

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Explanation

Incident cases represent **new cases** diagnosed in a given period of time. **Prevalent cases** are the **total number of cases** (both old and new) at a particular point in time. For a non-transmissible condition such as chronic lymphocytic leukemia (CLL), the number of incident cases will **not** be changed by any kind of treatment because the disease has already developed when the treatment is started (and treatment of existing patients will not prevent new patients from developing CLL). Any treatment that prolongs survival but does not cure the disease will **increase** the number of prevalent cases due to an increase in the number of afflicted (but still living) individuals over time.

Differences in terminology may lead to confusion. Incident cases and prevalent cases are often referred to as simply "incidence" and "prevalence." Incidence can also represent the number of new cases divided by the population at risk over a period of time and can be converted into a rate (eg, annual incidence per 10,000 population). Prevalence typically refers to point prevalence (total number of cases at a particular point in time) as opposed to period prevalence (over a period of time). The specific meaning is often clear from the context.

Educational objective:

Incident cases represent new cases diagnosed in a given period of time. Prevalent cases are the total number of cases (both old and new) at a particular point in time. Any treatment that prolongs survival but does not cure the disease will increase prevalence due to an increase in the number of afflicted (but still living) individuals over time.

Biostatistics	Biostatistics & Epidemiology	Risk, rate, prevalence and incidence
Subject	System	Topic

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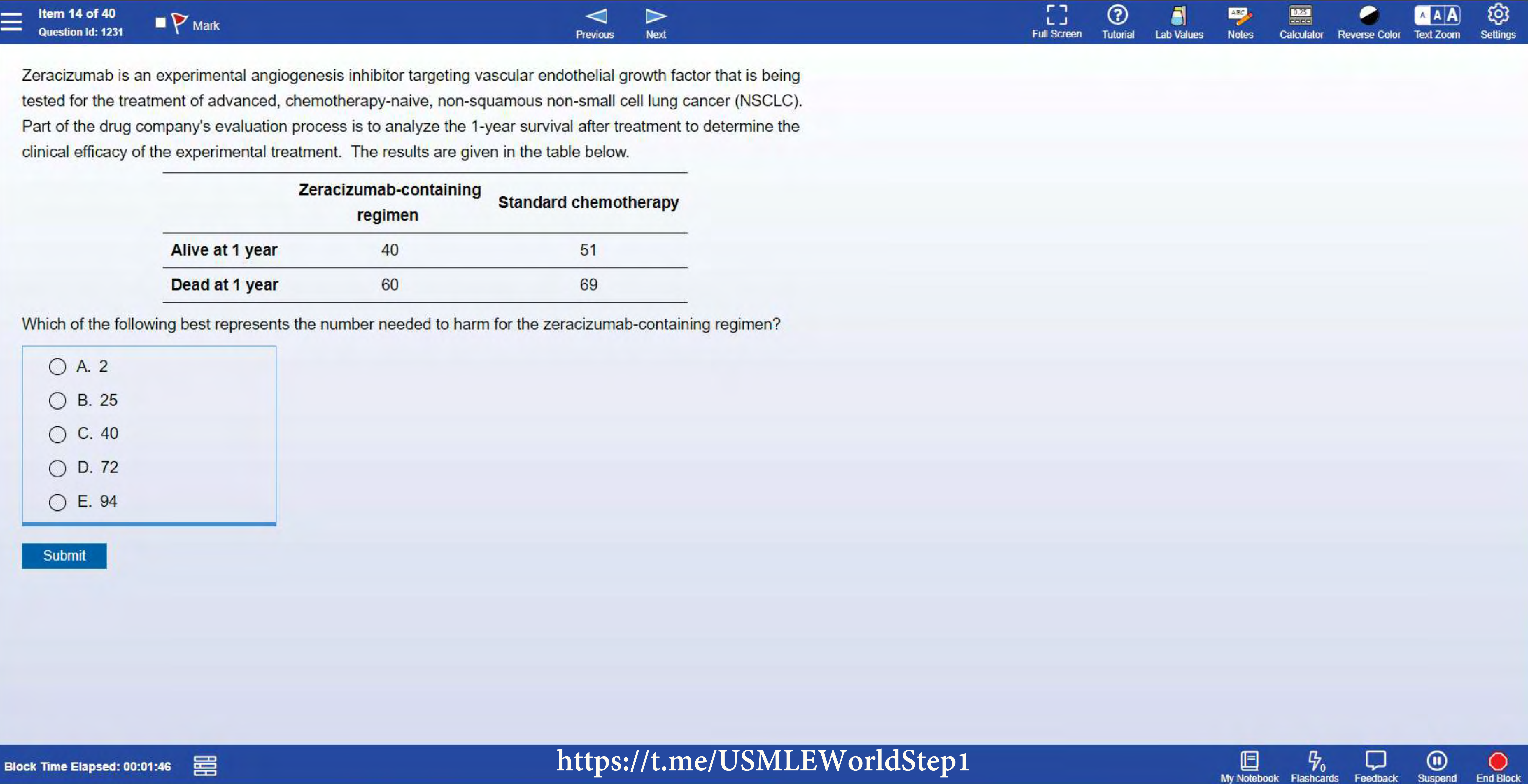
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Zeracizumab is an experimental angiogenesis inhibitor targeting vascular endothelial growth factor that is being tested for the treatment of advanced, chemotherapy-naive, non-squamous non-small cell lung cancer (NSCLC). Part of the drug company's evaluation process is to analyze the 1-year survival after treatment to determine the clinical efficacy of the experimental treatment. The results are given in the table below.

	Zeracizumab-containing regimen	**Standard chemotherapy**
Alive at 1 year	40	51
Dead at 1 year	60	69

Which of the following best represents the number needed to harm for the zeracizumab-containing regimen?

○ A. 2
○ B. 25
○ C. 40
○ D. 72
○ E. 94

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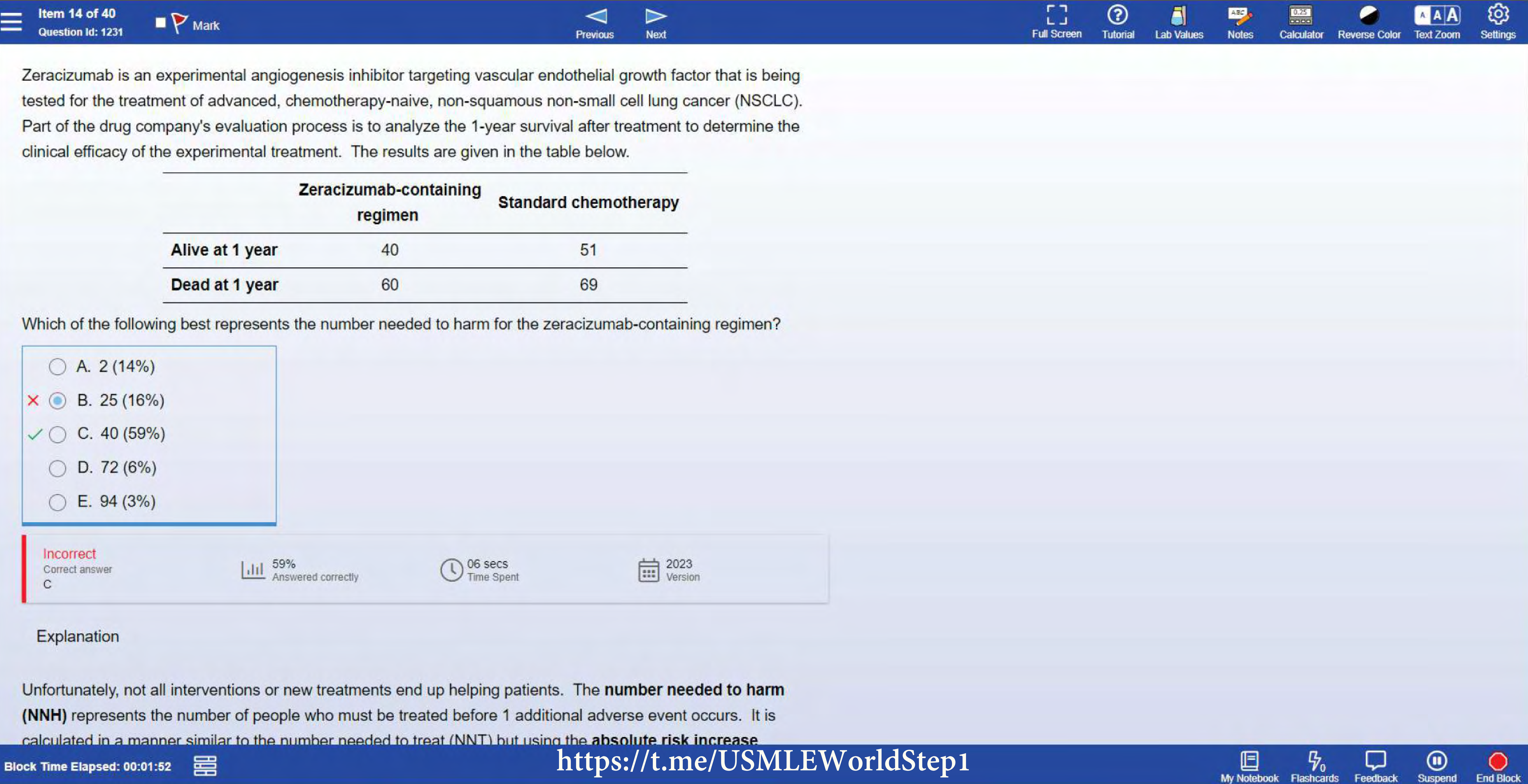
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	Zeracizumab-containing regimen	**Standard chemotherapy**
Alive at 1 year	40	51
Dead at 1 year	60	69

Which of the following best represents the number needed to harm for the zeracizumab-containing regimen?

○ A. 2 (14%)
✗ ● B. 25 (16%)
✓ ○ C. 40 (59%)
○ D. 72 (6%)
○ E. 94 (3%)

Incorrect
Correct answer
C

59%
Answered correctly

06 secs
Time Spent

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Explanation

Unfortunately, not all interventions or new treatments end up helping patients. The **number needed to harm (NNH)** represents the number of people who must be treated before 1 additional adverse event occurs. It is calculated in a manner similar to the number needed to treat (NNT) but using the **absolute risk increase**

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Unfortunately, not all interventions or new treatments end up helping patients. The **number needed to harm (NNH)** represents the number of people who must be treated before 1 additional adverse event occurs. It is calculated in a manner similar to the number needed to treat (NNT) but using the **absolute risk increase** (attributable risk) instead of the absolute risk reduction:

NNH = 1 / Absolute risk increase

To determine the absolute risk increase, first **calculate the adverse event rate** (eg, death) in the experimental and control groups. In this case, the adverse event of interest is death at 1 year. There were 40 + 60 = 100 people treated with the experimental treatment (ie, zeracizumab-containing regimen); of those, 60 were dead at 1 year. Similarly, there were 51 + 69 = 120 people treated with standard chemotherapy; of those, 69 were dead at 1 year. Therefore:

Adverse event rate in experimental group = 60 / 100 = 0.60 (ie, 60%)
Adverse event rate in control group = 69 / 120 = 0.575 (ie, 57.5%)

The absolute risk increase can then be calculated by **subtracting** the adverse event rate in the control group from the adverse event rate in the treatment group:

Absolute risk increase = 0.60 – 0.575 = 0.025 (ie, 2.5%)

The absolute risk increase attributable to the treatment is **2.5%** (60% risk of being dead at 1 year in the treatment group compared to 57.5% in the control group). The NNH then is simply the **inverse** of the absolute risk increase:

NNH = 1 / 0.025 = 40

This result indicates that, on average, **40 patients need to be treated** with a zeracizumab-containing regimen for 1 additional person to experience an adverse event (ie, death in 1 year).

Note that the data is NOT presented in the standard format of a contingency (2 × 2) table, so care should be exercised in selecting the appropriate values and applying the formulas (see alternate solution).

Educational objective:

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Adverse event rate in control group = 69 / 120 = 0.575 (ie, 57.5%)

The absolute risk increase can then be calculated by **subtracting** the adverse event rate in the control group from the adverse event rate in the treatment group:

Absolute risk increase = 0.60 – 0.575 = 0.025 (ie, 2.5%)

The absolute risk increase attributable to the treatment is **2.5%** (60% risk of being dead at 1 year in the treatment group compared to 57.5% in the control group). The NNH then is simply the **inverse** of the absolute risk increase:

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Note that the data is NOT presented in the standard format of a contingency (2 × 2) table, so care should be exercised in selecting the appropriate values and applying the formulas (see alternate solution).

Educational objective:

The number needed to harm (NNH) represents the number of people who must be treated before 1 additional adverse event occurs. In order to calculate NNH, the absolute risk increase between the treatment and control groups must be known: NNH = 1 / Absolute risk increase

Biostatistics	Biostatistics & Epidemiology	Number Needed To Treat
Subject	System	Topic

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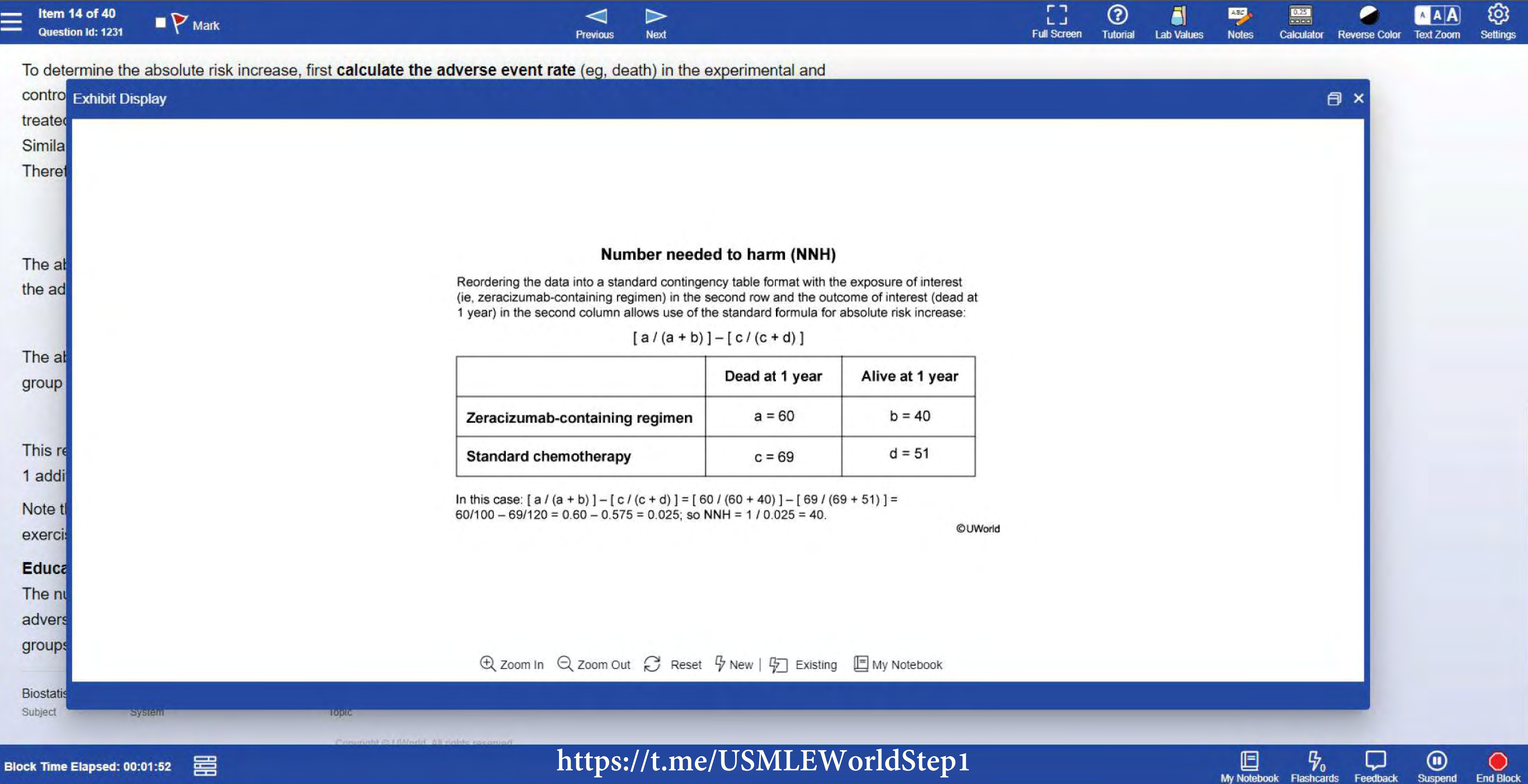
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To determine the absolute risk increase, first **calculate the adverse event rate** (eg, death) in the experimental and

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Number needed to harm (NNH)

Reordering the data into a standard contingency table format with the exposure of interest (ie, zeracizumab-containing regimen) in the second row and the outcome of interest (dead at 1 year) in the second column allows use of the standard formula for absolute risk increase:

$$[\, a / (a + b) \,] - [\, c / (c + d) \,]$$

	Dead at 1 year	**Alive at 1 year**
Zeracizumab-containing regimen	a = 60	b = 40
Standard chemotherapy	c = 69	d = 51

In this case: $[\, a / (a + b) \,] - [\, c / (c + d) \,] = [\, 60 / (60 + 40) \,] - [\, 69 / (69 + 51) \,] = 60/100 - 69/120 = 0.60 - 0.575 = 0.025$; so NNH = $1 / 0.025 = 40$.

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Biostatis

Subject

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Topic

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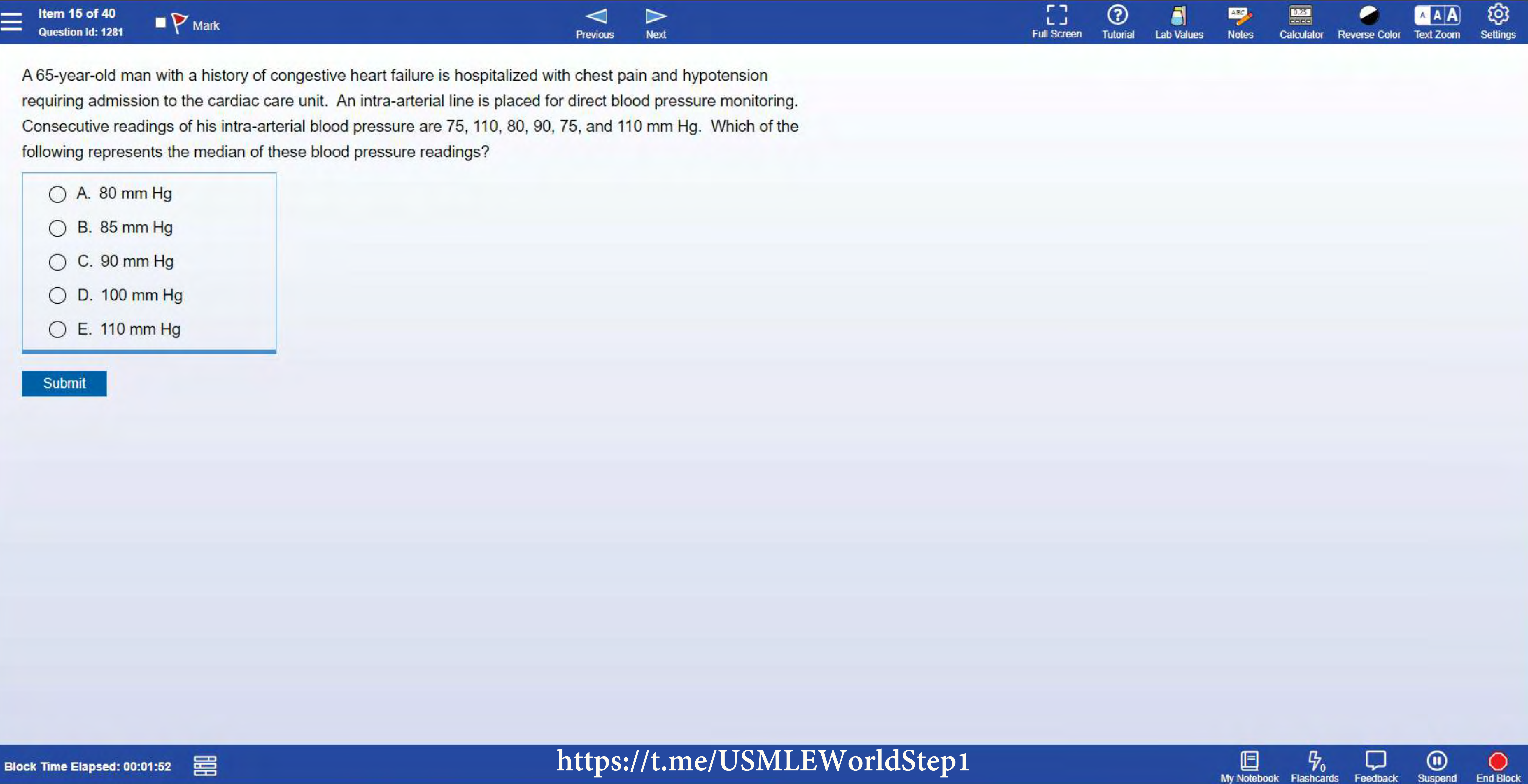
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A 65-year-old man with a history of congestive heart failure is hospitalized with chest pain and hypotension requiring admission to the cardiac care unit. An intra-arterial line is placed for direct blood pressure monitoring. Consecutive readings of his intra-arterial blood pressure are 75, 110, 80, 90, 75, and 110 mm Hg. Which of the following represents the median of these blood pressure readings?

○ A. 80 mm Hg
○ B. 85 mm Hg
○ C. 90 mm Hg
○ D. 100 mm Hg
○ E. 110 mm Hg

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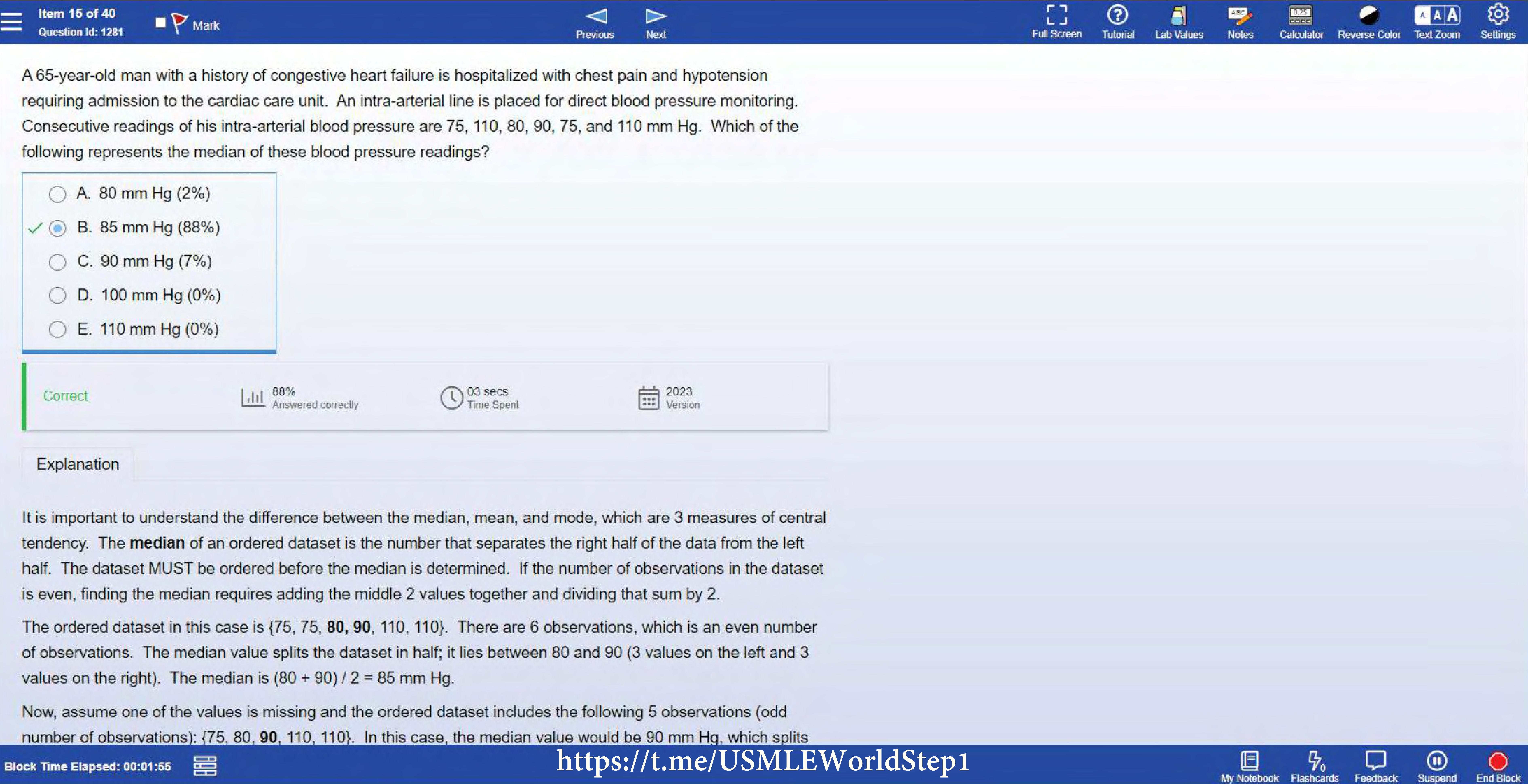
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A 65-year-old man with a history of congestive heart failure is hospitalized with chest pain and hypotension requiring admission to the cardiac care unit. An intra-arterial line is placed for direct blood pressure monitoring. Consecutive readings of his intra-arterial blood pressure are 75, 110, 80, 90, 75, and 110 mm Hg. Which of the following represents the median of these blood pressure readings?

○ A. 80 mm Hg (2%)
✓ ● B. 85 mm Hg (88%)
○ C. 90 mm Hg (7%)
○ D. 100 mm Hg (0%)
○ E. 110 mm Hg (0%)

Correct
88% Answered correctly
03 secs Time Spent
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Explanation

It is important to understand the difference between the median, mean, and mode, which are 3 measures of central tendency. The **median** of an ordered dataset is the number that separates the right half of the data from the left half. The dataset MUST be ordered before the median is determined. If the number of observations in the dataset is even, finding the median requires adding the middle 2 values together and dividing that sum by 2.

The ordered dataset in this case is {75, 75, **80, 90**, 110, 110}. There are 6 observations, which is an even number of observations. The median value splits the dataset in half; it lies between 80 and 90 (3 values on the left and 3 values on the right). The median is (80 + 90) / 2 = 85 mm Hg.

Now, assume one of the values is missing and the ordered dataset includes the following 5 observations (odd number of observations): {75, 80, **90**, 110, 110}. In this case, the median value would be 90 mm Hg, which splits

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Explanation

It is important to understand the difference between the median, mean, and mode, which are 3 measures of central tendency. The **median** of an ordered dataset is the number that separates the right half of the data from the left half. The dataset MUST be ordered before the median is determined. If the number of observations in the dataset is even, finding the median requires adding the middle 2 values together and dividing that sum by 2.

The ordered dataset in this case is {75, 75, **80, 90**, 110, 110}. There are 6 observations, which is an even number of observations. The median value splits the dataset in half; it lies between 80 and 90 (3 values on the left and 3 values on the right). The median is (80 + 90) / 2 = 85 mm Hg.

Now, assume one of the values is missing and the ordered dataset includes the following 5 observations (odd number of observations): {75, 80, **90**, 110, 110}. In this case, the median value would be 90 mm Hg, which splits the dataset in half (2 values on the left and 2 values on the right).

(Choices A and D) The values 80 and 100 mm Hg are not measures of the center of the dataset.

(Choice C) To find the **mean** of a dataset, add all of the observations and divide that sum by the number of observations. In this case, the mean is (75 + 75 + 80 + 90 + 110 + 110) / 6 = 90 mm Hg.

(Choice E) Another measure of the center of a dataset is the mode. Finding the **mode** is easy because it is the most frequent value of a dataset. In our scenario, the dataset is "bimodal" because 75 and 110 mm Hg are each listed twice.

Educational objective:
The median is the value that is located in the precise center of an ordered dataset. It separates the right half of the data from the left half.

Biostatistics	Biostatistics & Epidemiology	Central tendency (mean, median, mode, outliers)
Subject	System	Topic

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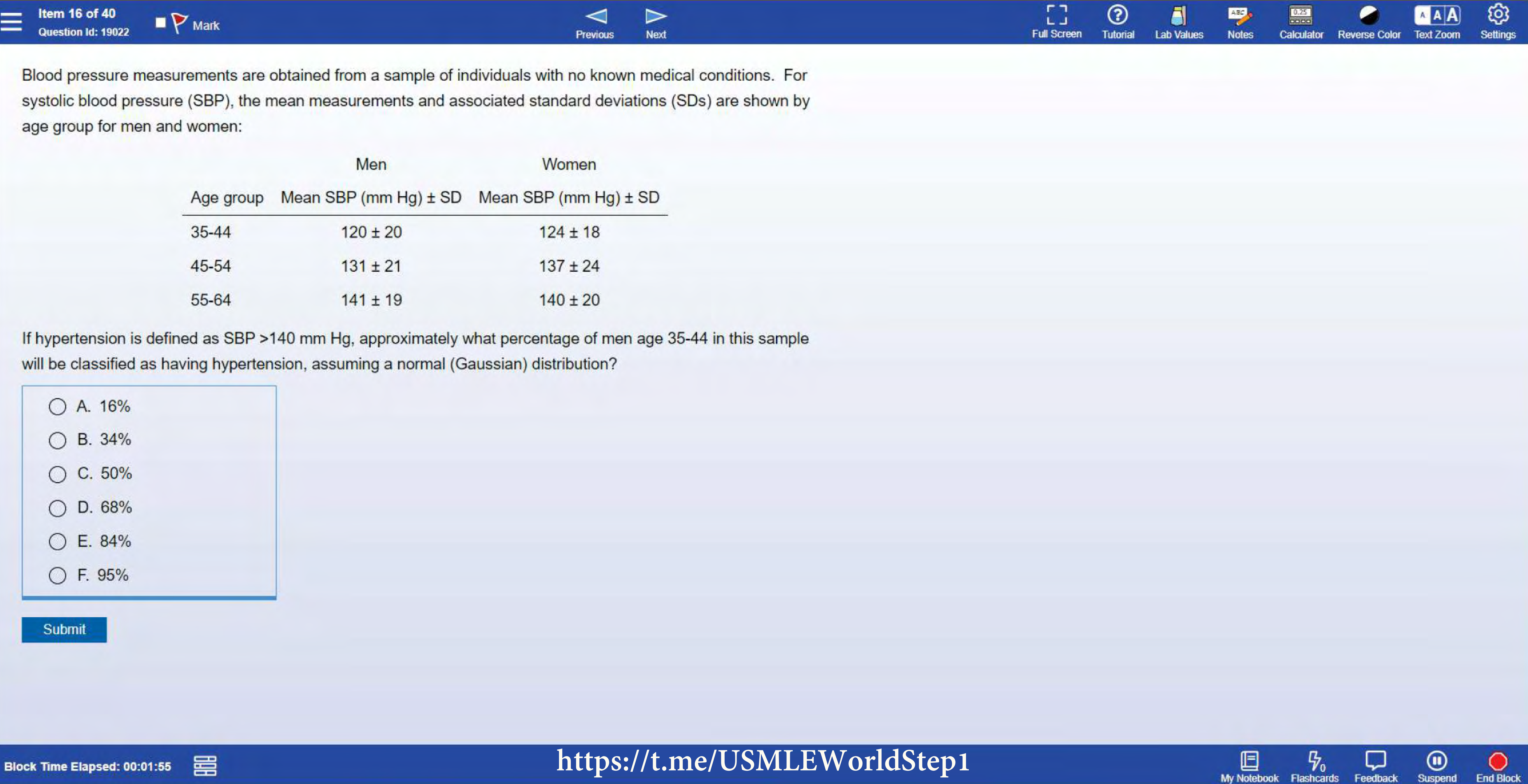
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Blood pressure measurements are obtained from a sample of individuals with no known medical conditions. For systolic blood pressure (SBP), the mean measurements and associated standard deviations (SDs) are shown by age group for men and women:

	Men	Women
Age group	Mean SBP (mm Hg) ± SD	Mean SBP (mm Hg) ± SD
35-44	120 ± 20	124 ± 18
45-54	131 ± 21	137 ± 24
55-64	141 ± 19	140 ± 20

If hypertension is defined as SBP >140 mm Hg, approximately what percentage of men age 35-44 in this sample will be classified as having hypertension, assuming a normal (Gaussian) distribution?

- ○ A. 16%
- ○ B. 34%
- ○ C. 50%
- ○ D. 68%
- ○ E. 84%
- ○ F. 95%

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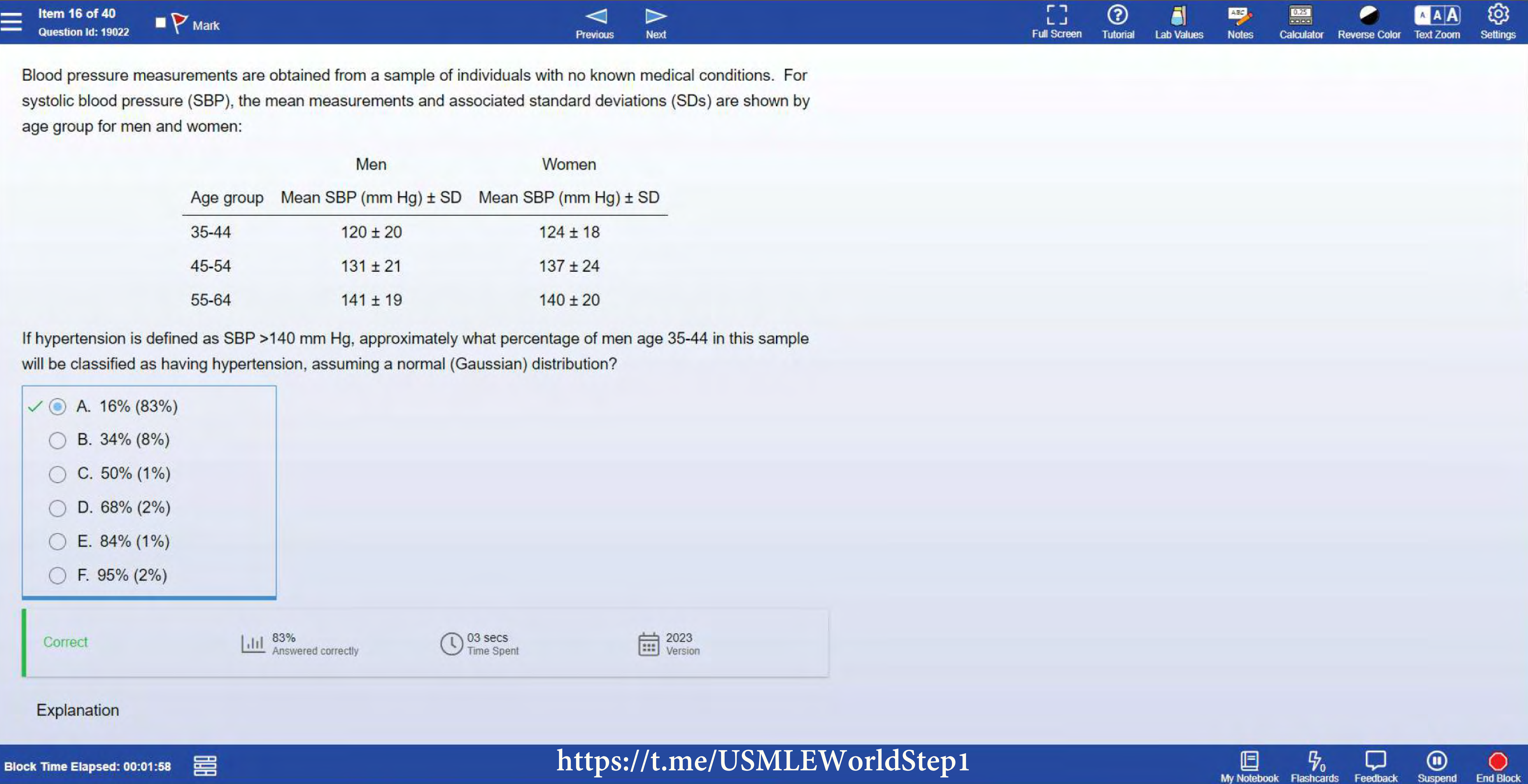
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Age group	Mean SBP (mm Hg) ± SD	Mean SBP (mm Hg) ± SD
35-44	120 ± 20	124 ± 18
45-54	131 ± 21	137 ± 24
55-64	141 ± 19	140 ± 20

If hypertension is defined as SBP >140 mm Hg, approximately what percentage of men age 35-44 in this sample will be classified as having hypertension, assuming a normal (Gaussian) distribution?

- ✓ ● A. 16% (83%)
- ○ B. 34% (8%)
- ○ C. 50% (1%)
- ○ D. 68% (2%)
- ○ E. 84% (1%)
- ○ F. 95% (2%)

Correct

83%
Answered correctly

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Explanation

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Correct

Answered correctly

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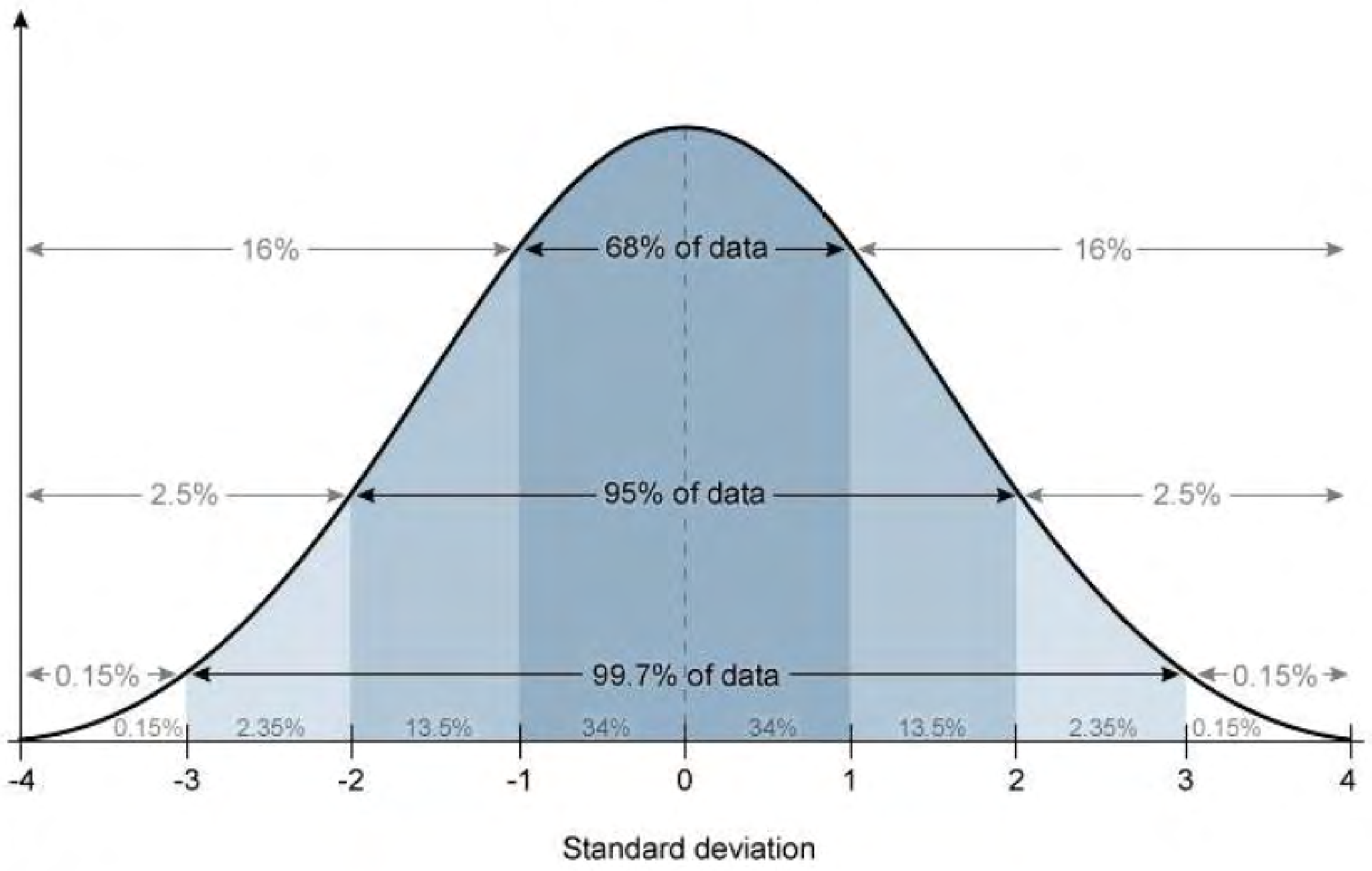
68-95-99.7 rule



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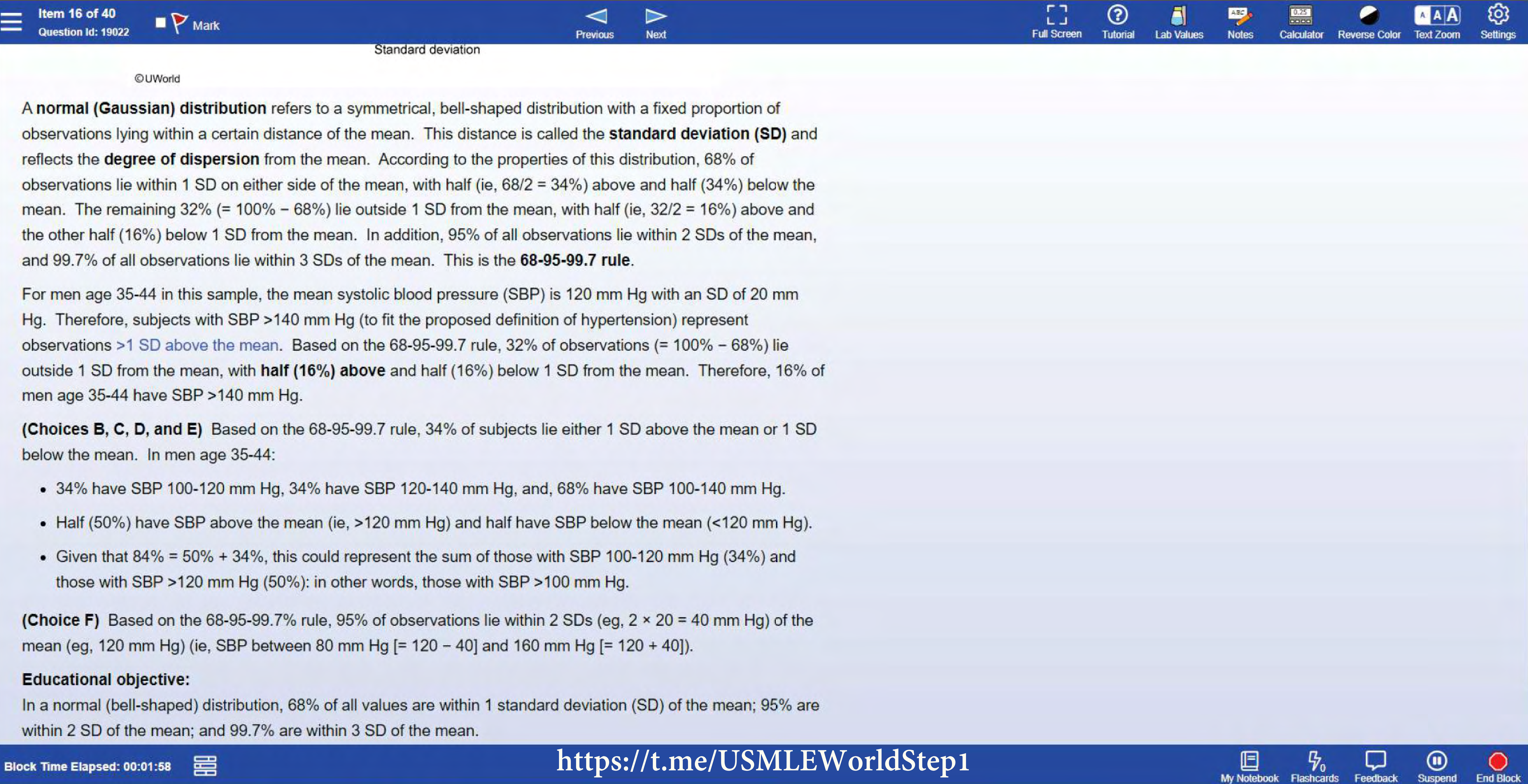
mean. The remaining 32% (= 100% − 68%) lie outside 1 SD from the mean, with half (ie, 32/2 = 16%) above and the other half (16%) below 1 SD from the mean. In addition, 95% of all observations lie within 2 SDs of the mean.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Standard deviation
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A **normal (Gaussian) distribution** refers to a symmetrical, bell-shaped distribution with a fixed proportion of observations lying within a certain distance of the mean. This distance is called the **standard deviation (SD)** and reflects the **degree of dispersion** from the mean. According to the properties of this distribution, 68% of observations lie within 1 SD on either side of the mean, with half (ie, 68/2 = 34%) above and half (34%) below the mean. The remaining 32% (= 100% − 68%) lie outside 1 SD from the mean, with half (ie, 32/2 = 16%) above and the other half (16%) below 1 SD from the mean. In addition, 95% of all observations lie within 2 SDs of the mean, and 99.7% of all observations lie within 3 SDs of the mean. This is the **68-95-99.7 rule**.

For men age 35-44 in this sample, the mean systolic blood pressure (SBP) is 120 mm Hg with an SD of 20 mm Hg. Therefore, subjects with SBP >140 mm Hg (to fit the proposed definition of hypertension) represent observations >1 SD above the mean. Based on the 68-95-99.7 rule, 32% of observations (= 100% − 68%) lie outside 1 SD from the mean, with **half (16%) above** and half (16%) below 1 SD from the mean. Therefore, 16% of men age 35-44 have SBP >140 mm Hg.

(Choices B, C, D, and E) Based on the 68-95-99.7 rule, 34% of subjects lie either 1 SD above the mean or 1 SD below the mean. In men age 35-44:

- 34% have SBP 100-120 mm Hg, 34% have SBP 120-140 mm Hg, and, 68% have SBP 100-140 mm Hg.
- Half (50%) have SBP above the mean (ie, >120 mm Hg) and half have SBP below the mean (<120 mm Hg).
- Given that 84% = 50% + 34%, this could represent the sum of those with SBP 100-120 mm Hg (34%) and those with SBP >120 mm Hg (50%): in other words, those with SBP >100 mm Hg.

(Choice F) Based on the 68-95-99.7% rule, 95% of observations lie within 2 SDs (eg, 2 × 20 = 40 mm Hg) of the mean (eg, 120 mm Hg) (ie, SBP between 80 mm Hg [= 120 − 40] and 160 mm Hg [= 120 + 40]).

Educational objective:

In a normal (bell-shaped) distribution, 68% of all values are within 1 standard deviation (SD) of the mean; 95% are within 2 SD of the mean; and 99.7% are within 3 SD of the mean.

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observations lying within a certain distance of the mean. This distance is called the **standard deviation (SD)** and reflects the **degree of dispersion** from the mean. According to the properties of this distribution, 68% of observations lie within 1 SD on either side of the mean, with half (ie, 68/2 = 34%) above and half (34%) below the mean. The remaining 32% (= 100% − 68%) lie outside 1 SD from the mean, with half (ie, 32/2 = 16%) above and the other half (16%) below 1 SD from the mean. In addition, 95% of all observations lie within 2 SDs of the mean, and 99.7% of all observations lie within 3 SDs of the mean. This is the **68-95-99.7 rule**.

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(Choices B, C, D, and E) Based on the 68-95-99.7 rule, 34% of subjects lie either 1 SD above the mean or 1 SD below the mean. In men age 35-44:

- 34% have SBP 100-120 mm Hg, 34% have SBP 120-140 mm Hg, and, 68% have SBP 100-140 mm Hg.
- Half (50%) have SBP above the mean (ie, >120 mm Hg) and half have SBP below the mean (<120 mm Hg).
- Given that 84% = 50% + 34%, this could represent the sum of those with SBP 100-120 mm Hg (34%) and those with SBP >120 mm Hg (50%): in other words, those with SBP >100 mm Hg.

(Choice F) Based on the 68-95-99.7% rule, 95% of observations lie within 2 SDs (eg, 2 × 20 = 40 mm Hg) of the mean (eg, 120 mm Hg) (ie, SBP between 80 mm Hg [= 120 − 40] and 160 mm Hg [= 120 + 40]).

Educational objective:

In a normal (bell-shaped) distribution, 68% of all values are within 1 standard deviation (SD) of the mean; 95% are within 2 SD of the mean; and 99.7% are within 3 SD of the mean.

References

- Our obsession with normal values.

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observations lying within a certain distance of the mean. This distance is called the **standard deviation (SD)** and

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- Our obsession with normal values.

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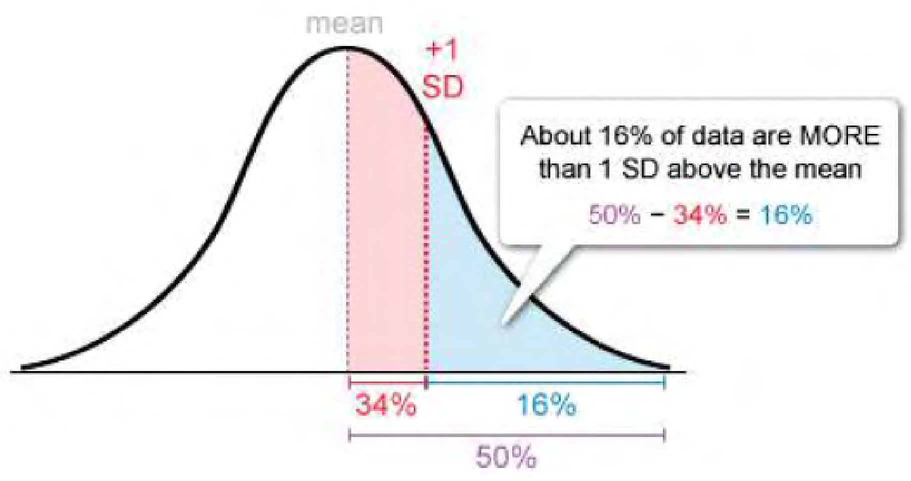
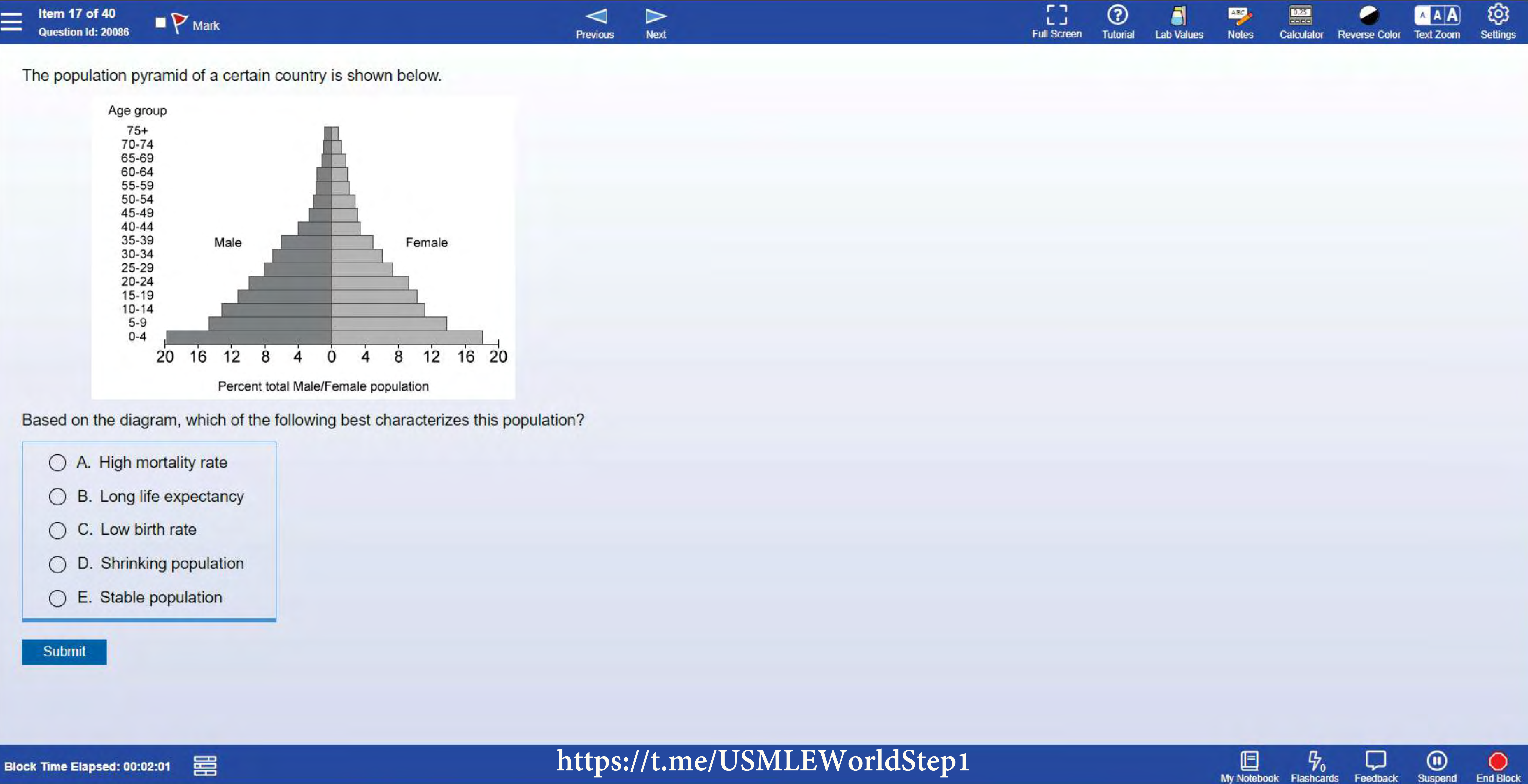


About 16% of data are MORE than 1 SD above the mean

50% − 34% = 16%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Age group
75+
70-74
65-69
60-64
55-59
50-54
45-49
40-44
35-39
30-34
25-29
20-24
15-19
10-14
5-9
0-4
Male
Female
20 16 12 8 4 0 4 8 12 16 20
Percent total Male/Female population
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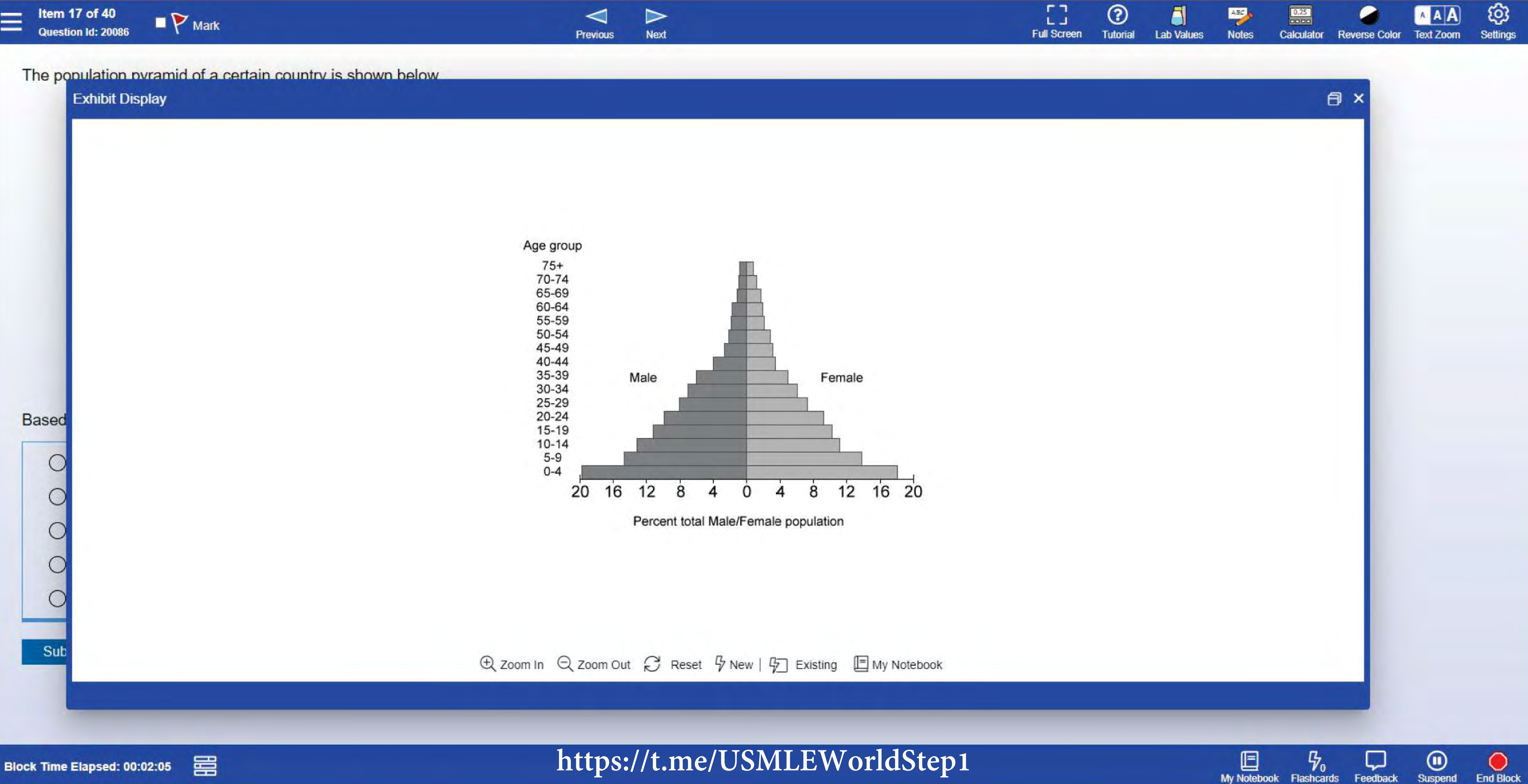
The population pyramid of a certain country is shown below.

Based on the diagram, which of the following best characterizes this population?

○ A. High mortality rate
○ B. Long life expectancy
○ C. Low birth rate
○ D. Shrinking population
○ E. Stable population



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The population pyramid of a certain country is shown below.

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Age group
75+
70-74
65-69
60-64
55-59
50-54
45-49
40-44
35-39
30-34
25-29
20-24
15-19
10-14
5-9
0-4
Male
Female
20 16 12 8 4 0 4 8 12 16 20
Percent total Male/Female population
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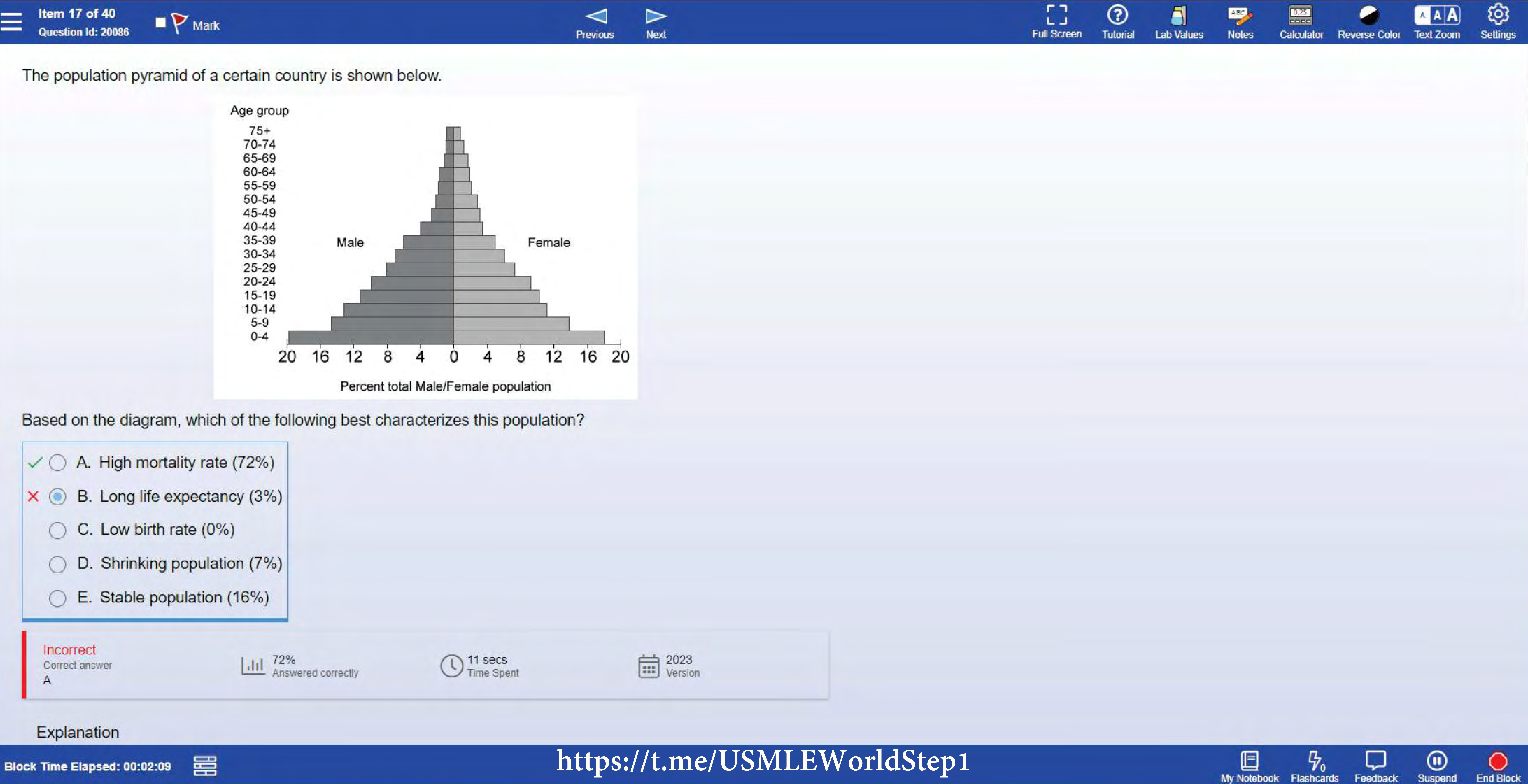
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The population pyramid of a certain country is shown below.

Age group
75+
70-74
65-69
60-64
55-59
50-54
45-49
40-44
35-39
30-34
25-29
20-24
15-19
10-14
5-9
0-4
Male
Female
20 16 12 8 4 0 4 8 12 16 20
Percent total Male/Female population

Based on the diagram, which of the following best characterizes this population?

✓ ○ A. High mortality rate (72%)
✗ ● B. Long life expectancy (3%)
○ C. Low birth rate (0%)
○ D. Shrinking population (7%)
○ E. Stable population (16%)

Incorrect
Correct answer
A

72%
Answered correctly

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Explanation

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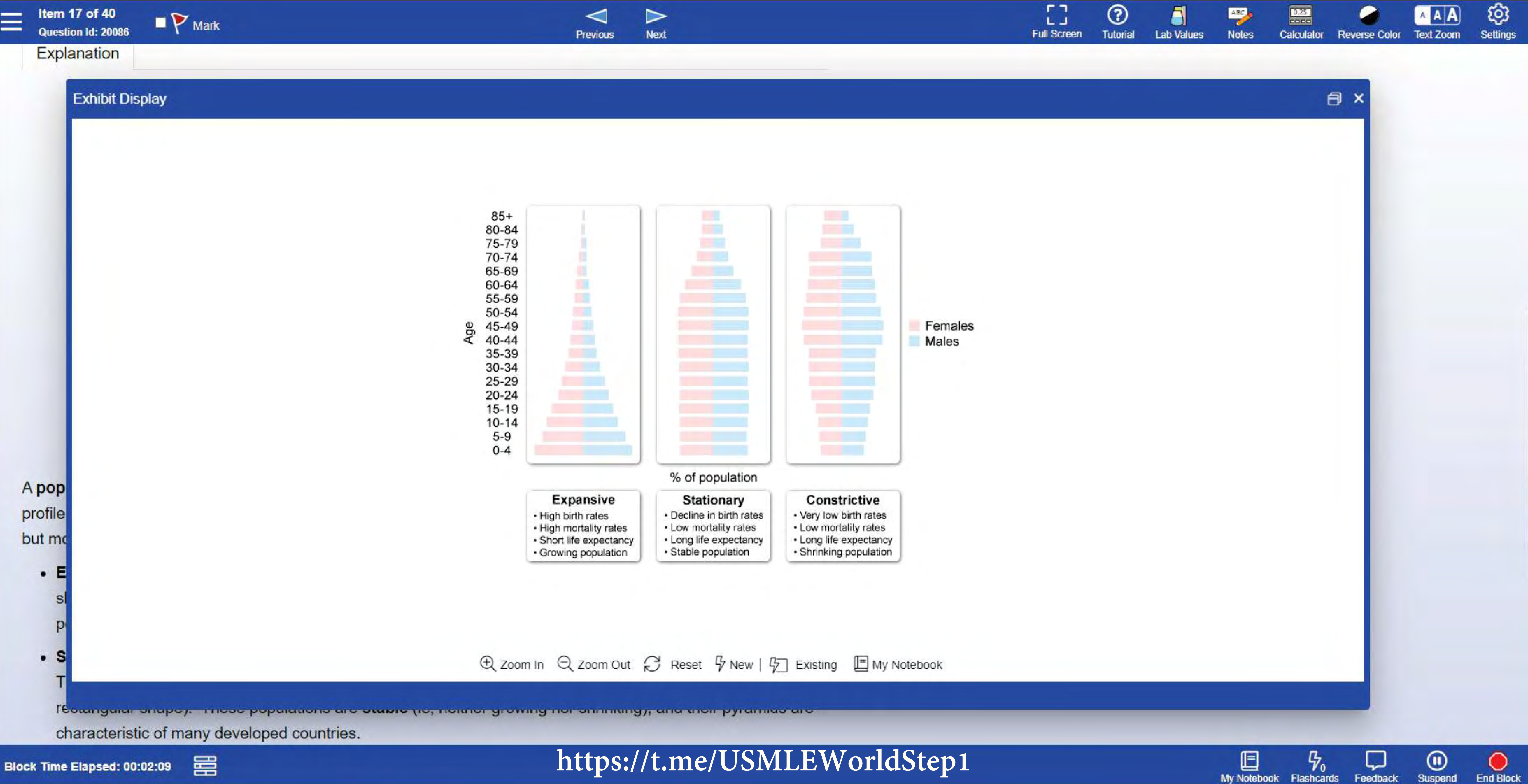
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Age
85+
80-84
75-79
70-74
65-69
60-64
55-59
50-54
45-49
40-44
35-39
30-34
25-29
20-24
15-19
10-14
5-9
0-4
% of population
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Males
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Expansive
- High birth rates
- High mortality rates
- Short life expectancy
- Growing population

Stationary
- Decline in birth rates
- Low mortality rates
- Long life expectancy
- Stable population

Constrictive
- Very low birth rates
- Low mortality rates
- Long life expectancy
- Shrinking population

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  characteristic of many developed countries.

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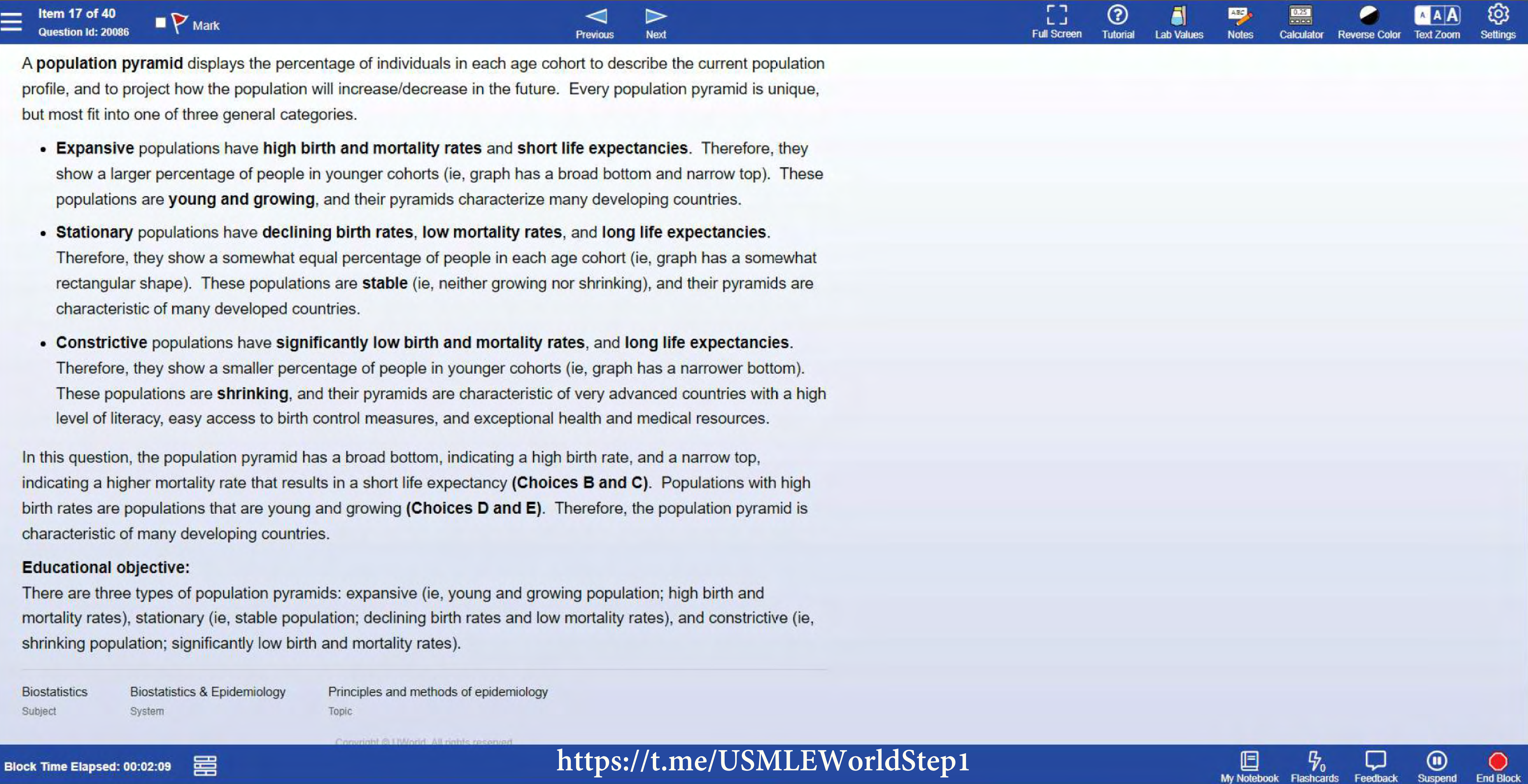

A **population pyramid** displays the percentage of individuals in each age cohort to describe the current population profile, and to project how the population will increase/decrease in the future. Every population pyramid is unique, but most fit into one of three general categories.

- **Expansive** populations have **high birth and mortality rates** and **short life expectancies**. Therefore, they show a larger percentage of people in younger cohorts (ie, graph has a broad bottom and narrow top). These populations are **young and growing**, and their pyramids characterize many developing countries.
- **Stationary** populations have **declining birth rates**, **low mortality rates**, and **long life expectancies**. Therefore, they show a somewhat equal percentage of people in each age cohort (ie, graph has a somewhat rectangular shape). These populations are **stable** (ie, neither growing nor shrinking), and their pyramids are characteristic of many developed countries.
- **Constrictive** populations have **significantly low birth and mortality rates**, and **long life expectancies**. Therefore, they show a smaller percentage of people in younger cohorts (ie, graph has a narrower bottom). These populations are **shrinking**, and their pyramids are characteristic of very advanced countries with a high level of literacy, easy access to birth control measures, and exceptional health and medical resources.

In this question, the population pyramid has a broad bottom, indicating a high birth rate, and a narrow top, indicating a higher mortality rate that results in a short life expectancy **(Choices B and C)**. Populations with high birth rates are populations that are young and growing **(Choices D and E)**. Therefore, the population pyramid is characteristic of many developing countries.

Educational objective:

There are three types of population pyramids: expansive (ie, young and growing population; high birth and mortality rates), stationary (ie, stable population; declining birth rates and low mortality rates), and constrictive (ie, shrinking population; significantly low birth and mortality rates).

Subject	System	Topic
Biostatistics	Biostatistics & Epidemiology	Principles and methods of epidemiology

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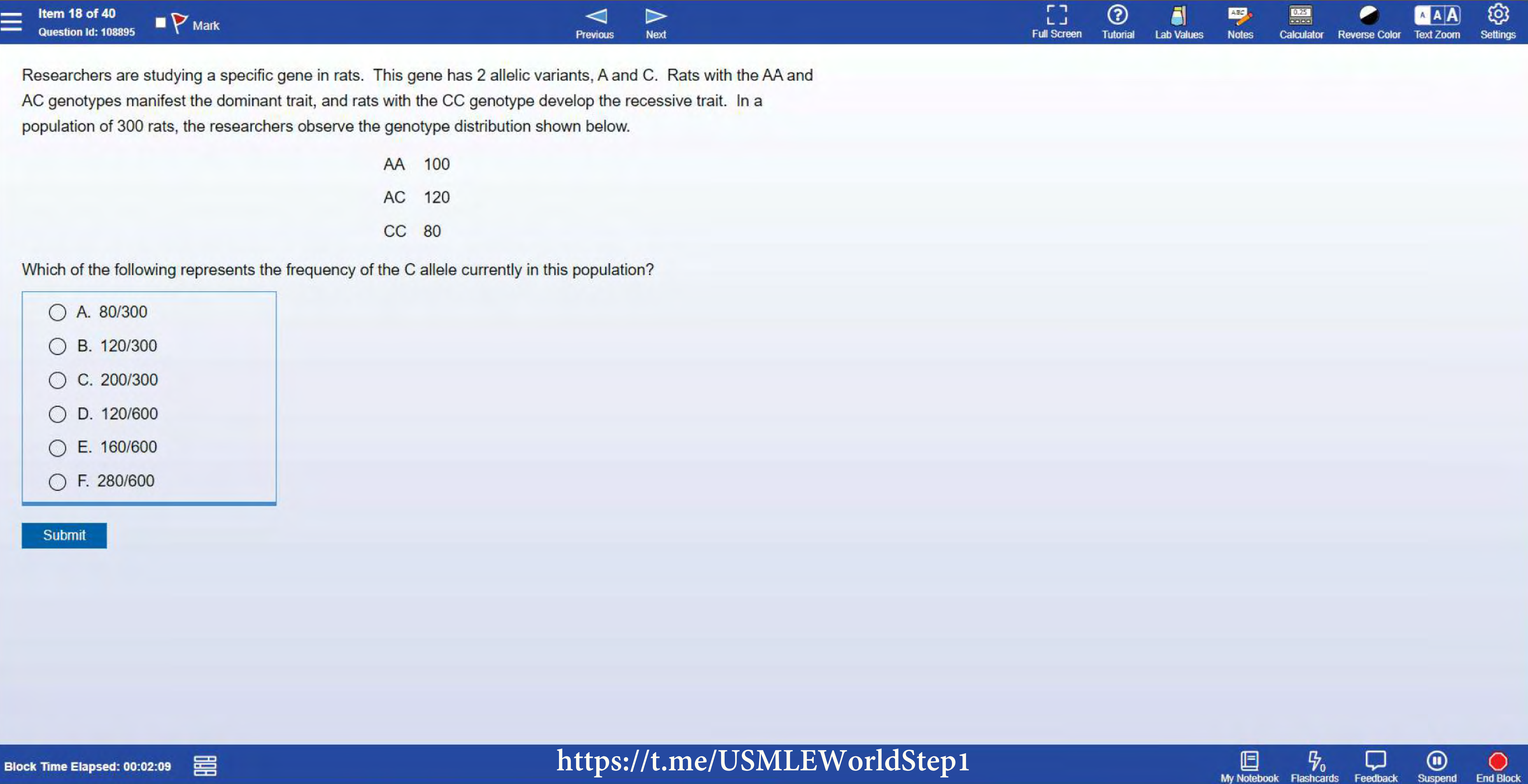
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Researchers are studying a specific gene in rats. This gene has 2 allelic variants, A and C. Rats with the AA and AC genotypes manifest the dominant trait, and rats with the CC genotype develop the recessive trait. In a population of 300 rats, the researchers observe the genotype distribution shown below.

AA	100
AC	120
CC	80

Which of the following represents the frequency of the C allele currently in this population?

○ A. 80/300
○ B. 120/300
○ C. 200/300
○ D. 120/600
○ E. 160/600
○ F. 280/600

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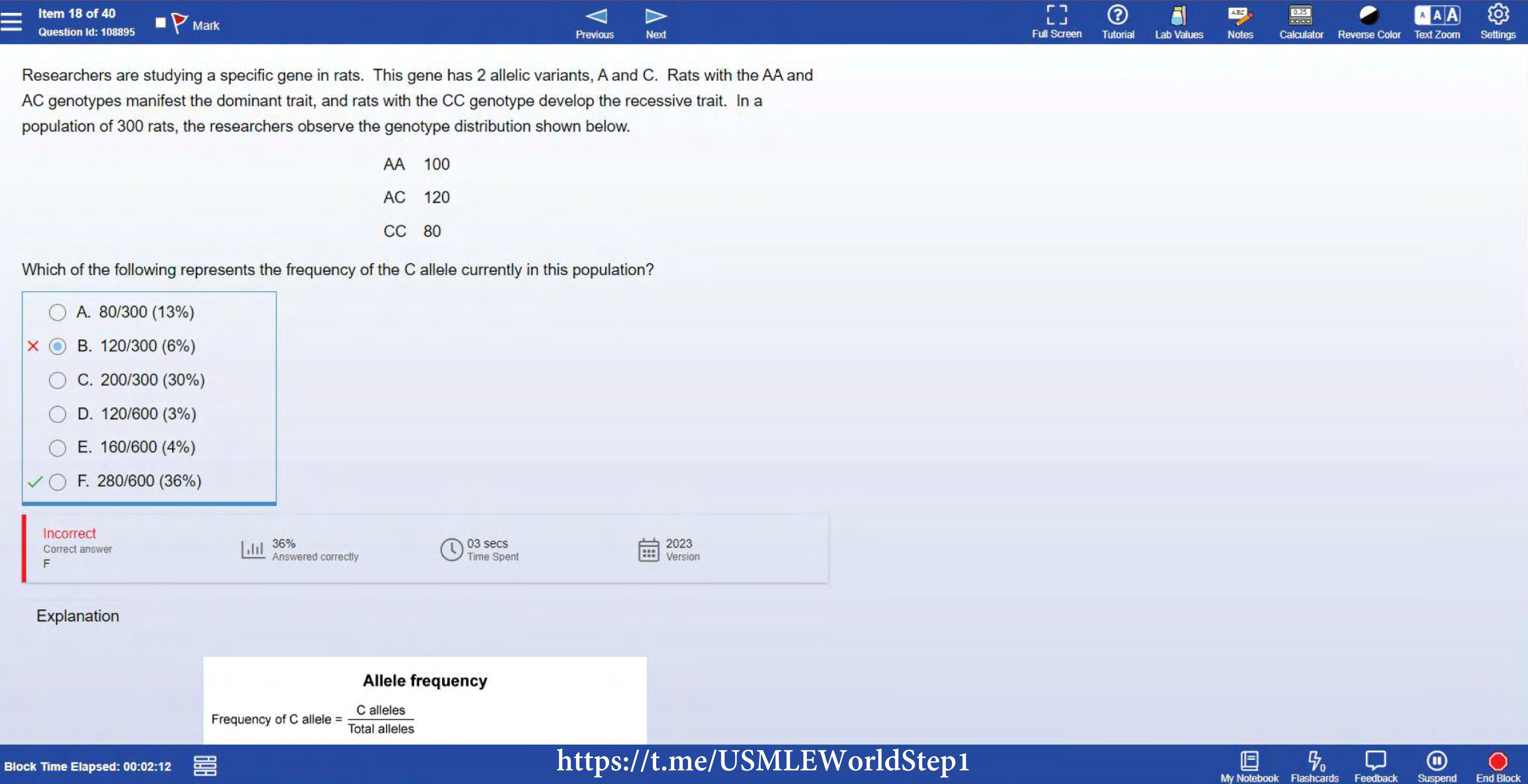
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Researchers are studying a specific gene in rats. This gene has 2 allelic variants, A and C. Rats with the AA and AC genotypes manifest the dominant trait, and rats with the CC genotype develop the recessive trait. In a population of 300 rats, the researchers observe the genotype distribution shown below.

AA	100
AC	120
CC	80

Which of the following represents the frequency of the C allele currently in this population?

- ○ A. 80/300 (13%)
- ✗ ● B. 120/300 (6%)
- ○ C. 200/300 (30%)
- ○ D. 120/600 (3%)
- ○ E. 160/600 (4%)
- ✓ ○ F. 280/600 (36%)

Incorrect
Correct answer
F

36%
Answered correctly

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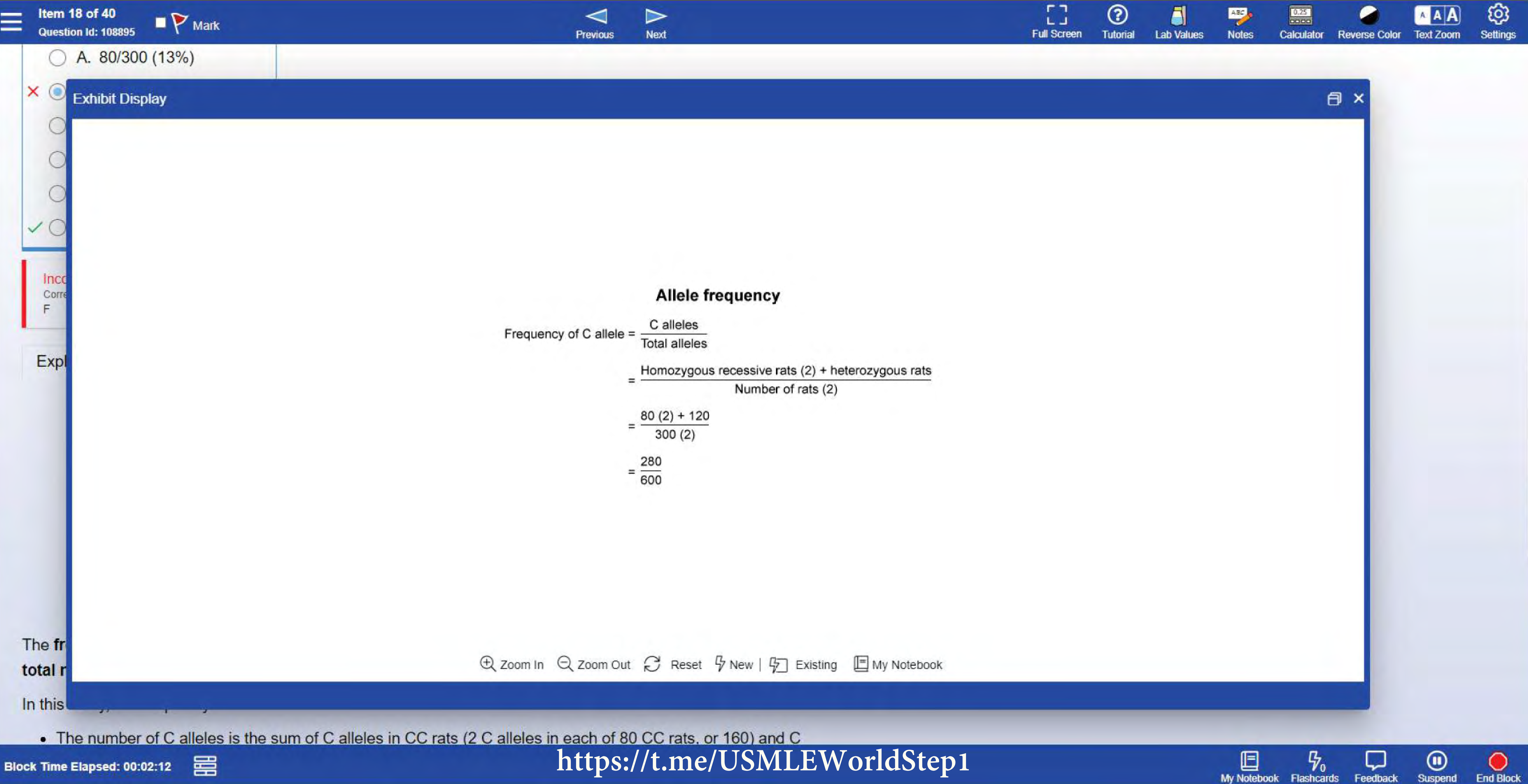
Explanation

Allele frequency

$$\text{Frequency of C allele} = \frac{\text{C alleles}}{\text{Total alleles}}$$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○ A. 80/300 (13%)

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Allele frequency

$$\text{Frequency of C allele} = \frac{\text{C alleles}}{\text{Total alleles}}$$

$$= \frac{\text{Homozygous recessive rats (2) + heterozygous rats}}{\text{Number of rats (2)}}$$

$$= \frac{80\ (2) + 120}{300\ (2)}$$

$$= \frac{280}{600}$$

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- The number of C alleles is the sum of C alleles in CC rats (2 C alleles in each of 80 CC rats, or 160) and C

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Allele frequency

$$\text{Frequency of C allele} = \frac{\text{C alleles}}{\text{Total alleles}}$$

$$= \frac{\text{Homozygous recessive rats (2) + heterozygous rats}}{\text{Number of rats (2)}}$$

$$= \frac{80\ (2) + 120}{300\ (2)}$$

$$= \frac{280}{600}$$

The **frequency of an allele** (eg, **C**) in a population is equal to the **number of that specific allele** divided by the **total number of alleles** (eg, **A + C**) in the population.

In this study, the frequency of the C allele is calculated as follows:

- The number of C alleles is the sum of C alleles in CC rats (2 C alleles in each of 80 CC rats, or 160) and C alleles in AC rats (1 C allele in each of 120 AC rats). This is **280 C alleles**.
- Because each rat has 2 alleles, there are **600 total alleles** in this population of 300 rats.

Therefore, the frequency of the C allele is **280/600 (Choices C, D, and E)**.

(Choices A and B) The values 80/300 and 120/300 represent the frequencies of the CC and AC genotypes, respectively, in this population, not the frequency of a specific allele.

Educational objective:
The frequency of an allele is equal to the number of that specific allele divided by the total number of alleles in the population.

Genetics	Biostatistics & Epidemiology	Population genetics
Subject	System	Topic

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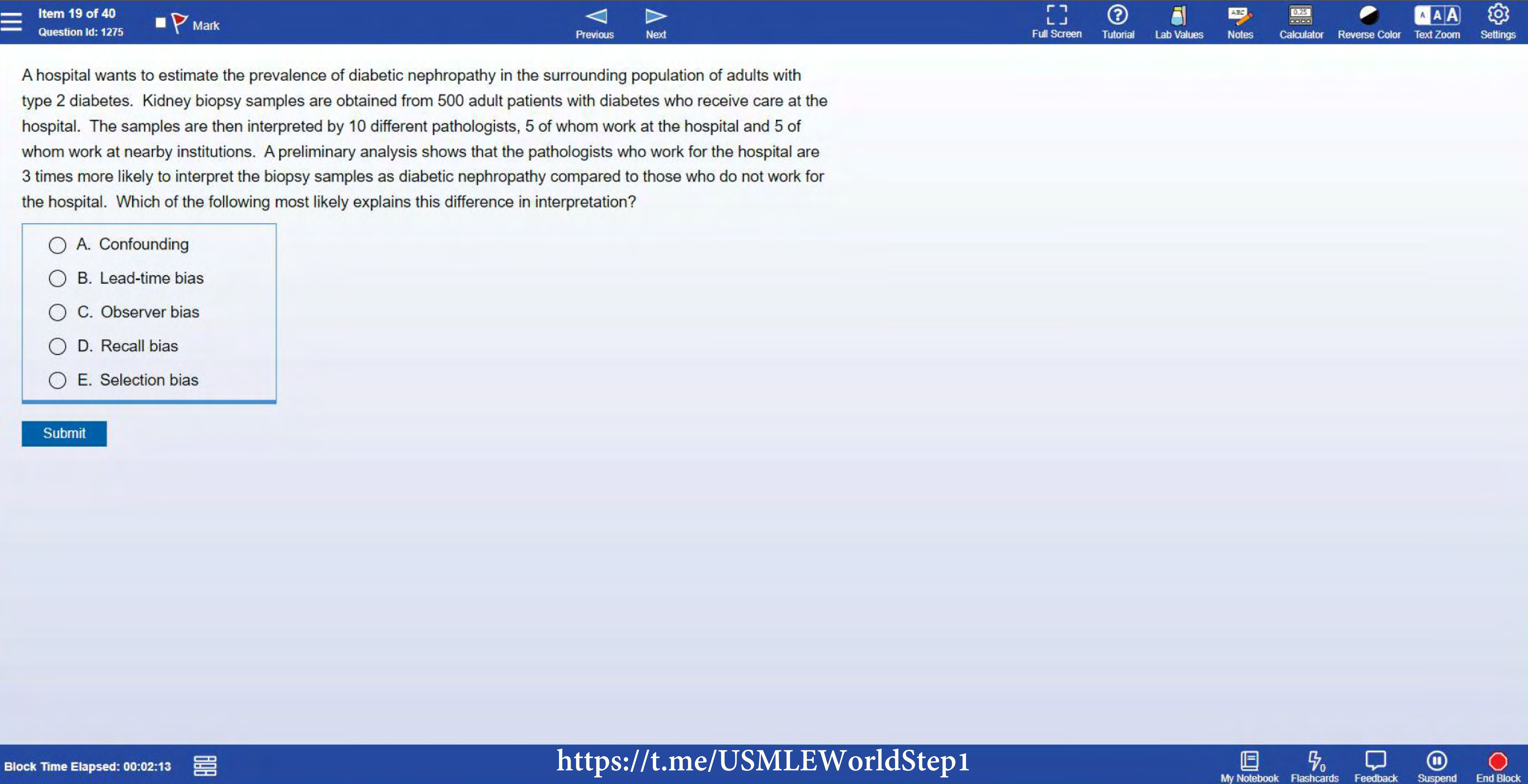
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A hospital wants to estimate the prevalence of diabetic nephropathy in the surrounding population of adults with type 2 diabetes. Kidney biopsy samples are obtained from 500 adult patients with diabetes who receive care at the hospital. The samples are then interpreted by 10 different pathologists, 5 of whom work at the hospital and 5 of whom work at nearby institutions. A preliminary analysis shows that the pathologists who work for the hospital are 3 times more likely to interpret the biopsy samples as diabetic nephropathy compared to those who do not work for the hospital. Which of the following most likely explains this difference in interpretation?

- ○ A. Confounding
- ○ B. Lead-time bias
- ○ C. Observer bias
- ○ D. Recall bias
- ○ E. Selection bias

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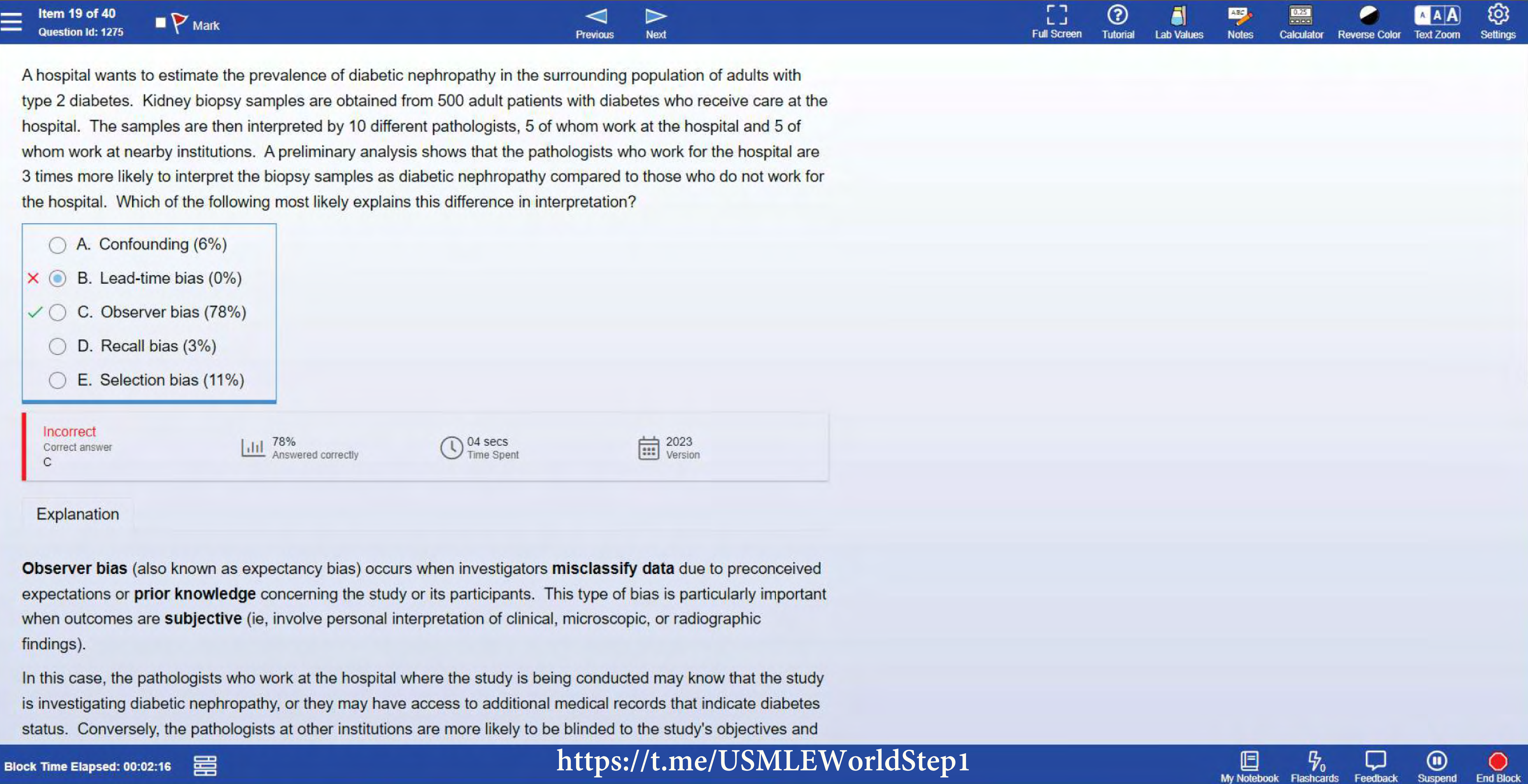
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○ A. Confounding (6%)
✗ ● B. Lead-time bias (0%)
✓ ○ C. Observer bias (78%)
○ D. Recall bias (3%)
○ E. Selection bias (11%)

Incorrect
Correct answer
C

78%
Answered correctly

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Explanation

Observer bias (also known as expectancy bias) occurs when investigators **misclassify data** due to preconceived expectations or **prior knowledge** concerning the study or its participants. This type of bias is particularly important when outcomes are **subjective** (ie, involve personal interpretation of clinical, microscopic, or radiographic findings).

In this case, the pathologists who work at the hospital where the study is being conducted may know that the study is investigating diabetic nephropathy, or they may have access to additional medical records that indicate diabetes status. Conversely, the pathologists at other institutions are more likely to be blinded to the study's objectives and

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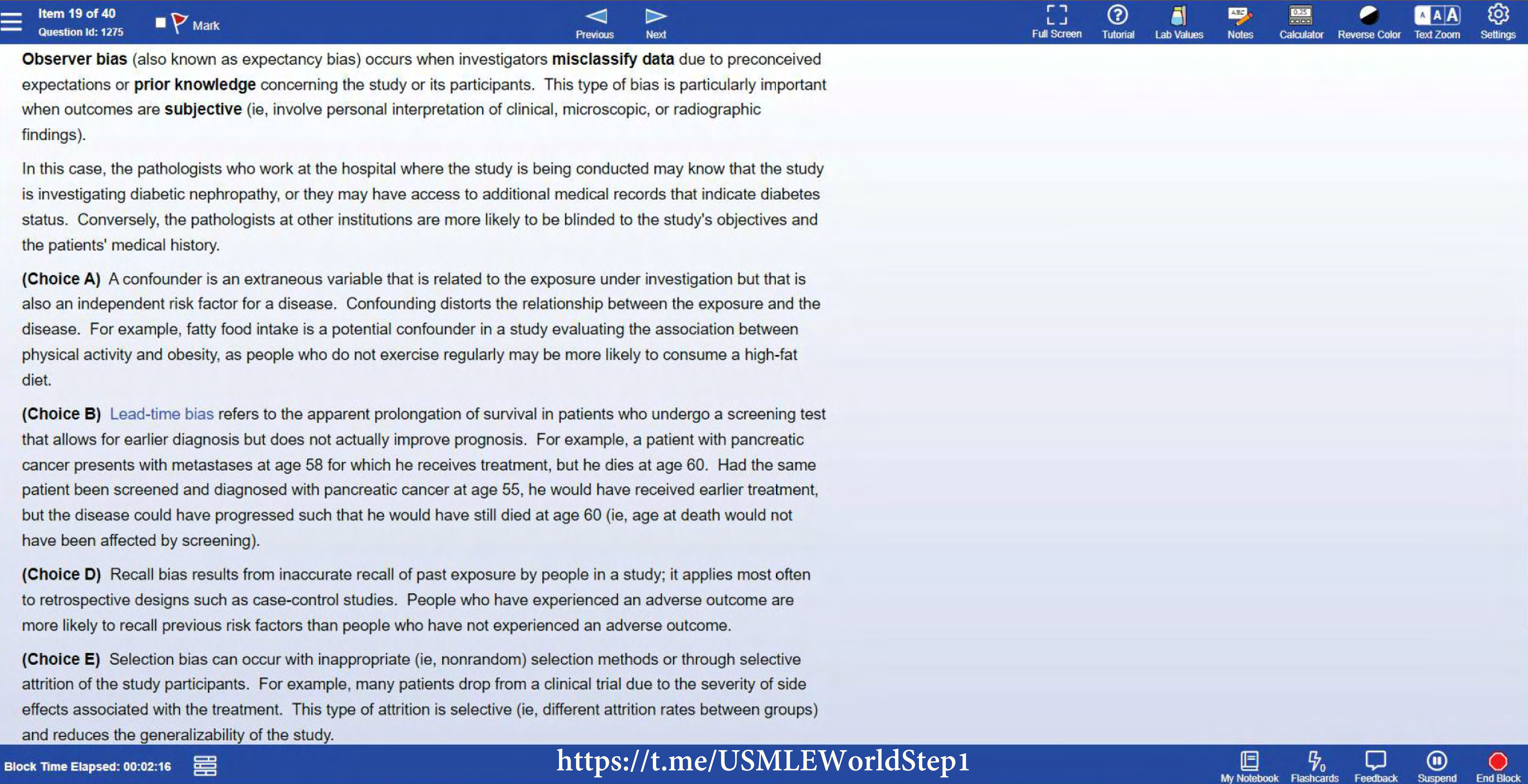

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(Choice A) A confounder is an extraneous variable that is related to the exposure under investigation but that is also an independent risk factor for a disease. Confounding distorts the relationship between the exposure and the disease. For example, fatty food intake is a potential confounder in a study evaluating the association between physical activity and obesity, as people who do not exercise regularly may be more likely to consume a high-fat diet.

(Choice B) Lead-time bias refers to the apparent prolongation of survival in patients who undergo a screening test that allows for earlier diagnosis but does not actually improve prognosis. For example, a patient with pancreatic cancer presents with metastases at age 58 for which he receives treatment, but he dies at age 60. Had the same patient been screened and diagnosed with pancreatic cancer at age 55, he would have received earlier treatment, but the disease could have progressed such that he would have still died at age 60 (ie, age at death would not have been affected by screening).

(Choice D) Recall bias results from inaccurate recall of past exposure by people in a study; it applies most often to retrospective designs such as case-control studies. People who have experienced an adverse outcome are more likely to recall previous risk factors than people who have not experienced an adverse outcome.

(Choice E) Selection bias can occur with inappropriate (ie, nonrandom) selection methods or through selective attrition of the study participants. For example, many patients drop from a clinical trial due to the severity of side effects associated with the treatment. This type of attrition is selective (ie, different attrition rates between groups) and reduces the generalizability of the study.

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Educational objective:

Observer bias occurs when the investigator's evaluation is affected by preconceived expectations or prior knowledge, typically leading to overestimation of the disease association or treatment effects. This type of bias can be reduced by conducting a blinded study in which observers are unaware of study details and patient characteristics that could unduly influence them.

Biostatistics	Biostatistics & Epidemiology	Bias
Subject	System	Topic

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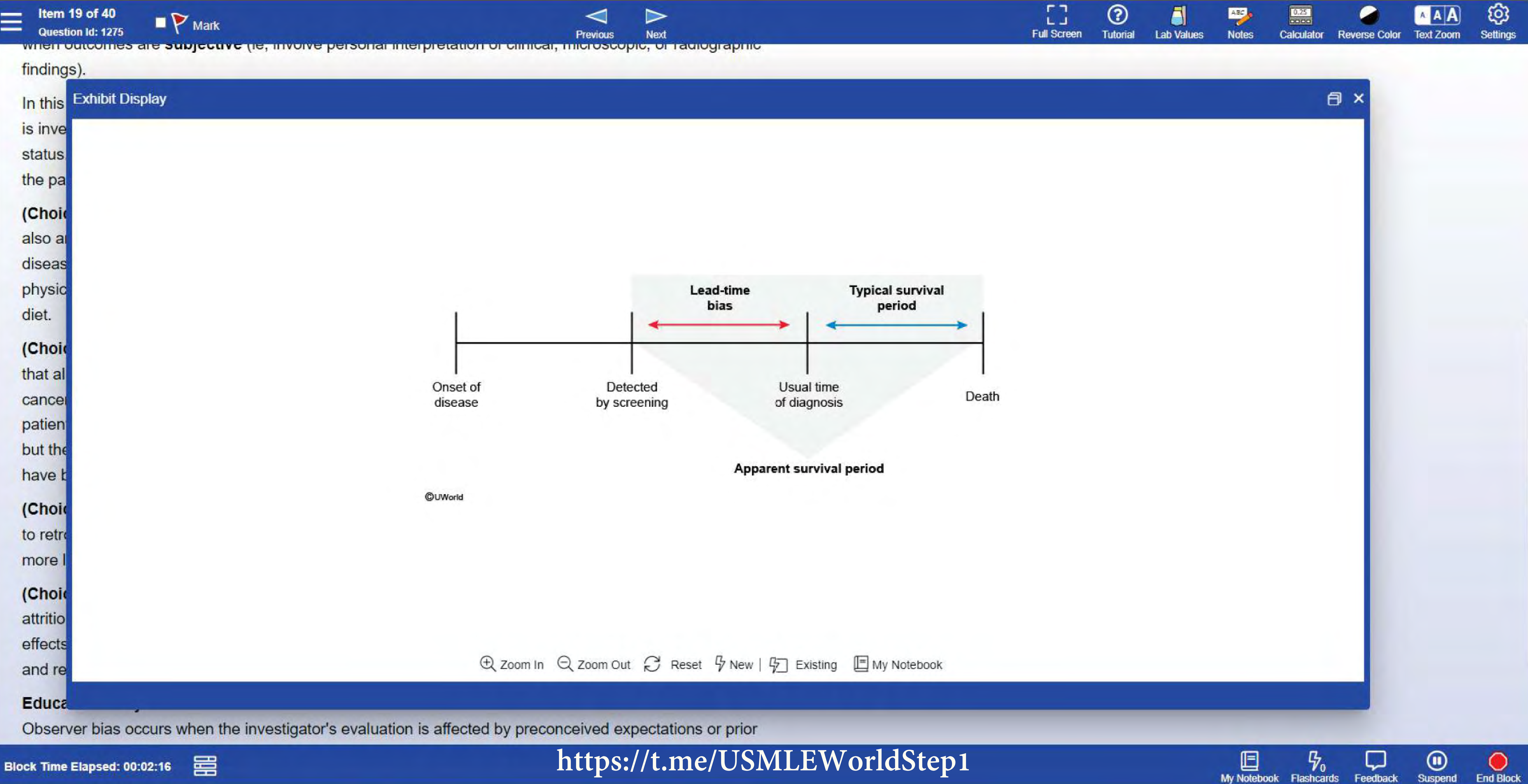
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Exhibit Display
Lead-time bias
Typical survival period
Onset of disease
Detected by screening
Usual time of diagnosis
Death
Apparent survival period
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when outcomes are **subjective** (ie, involve personal interpretation of clinical, microscopic, or radiographic findings).

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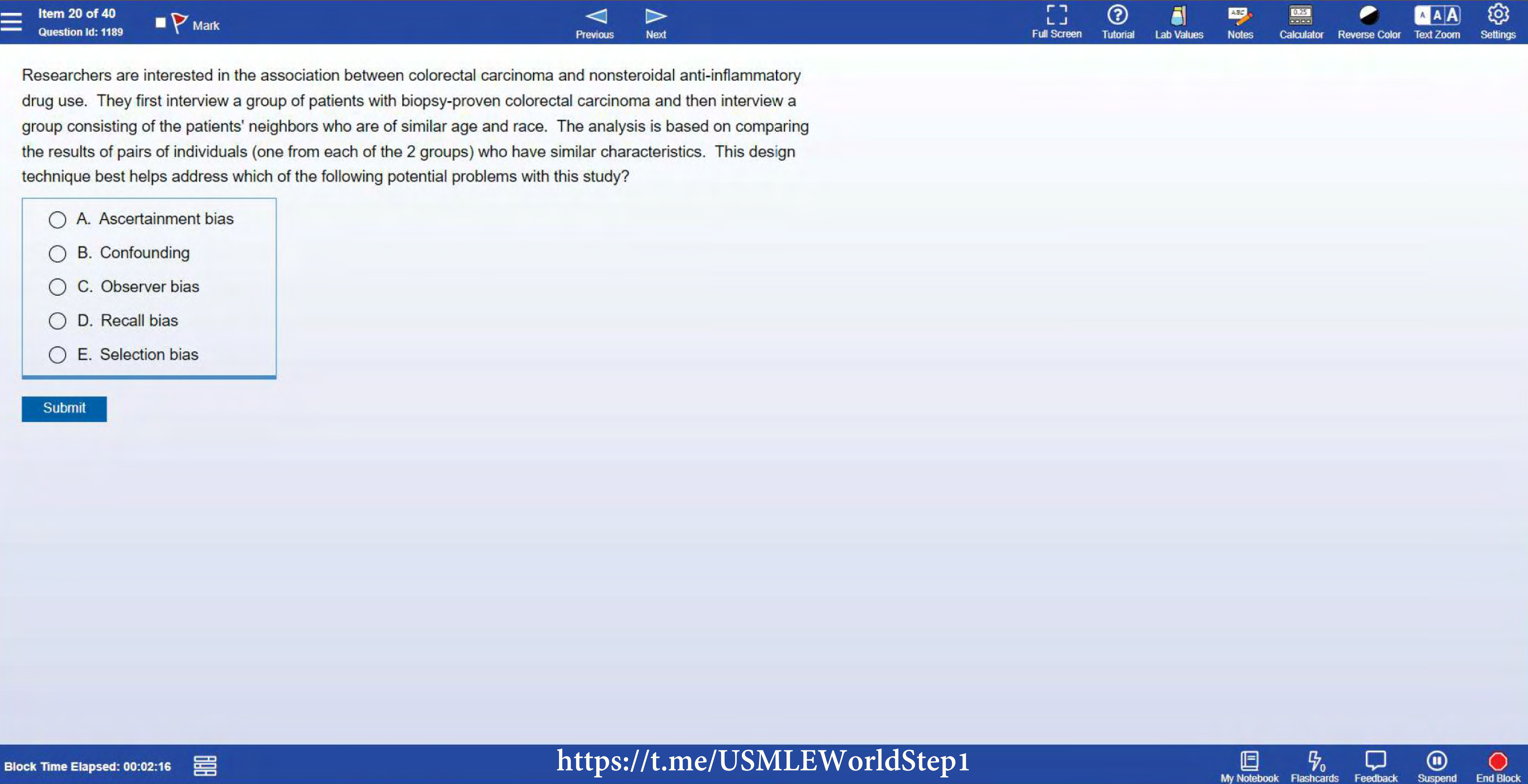
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Researchers are interested in the association between colorectal carcinoma and nonsteroidal anti-inflammatory drug use. They first interview a group of patients with biopsy-proven colorectal carcinoma and then interview a group consisting of the patients' neighbors who are of similar age and race. The analysis is based on comparing the results of pairs of individuals (one from each of the 2 groups) who have similar characteristics. This design technique best helps address which of the following potential problems with this study?

○ A. Ascertainment bias
○ B. Confounding
○ C. Observer bias
○ D. Recall bias
○ E. Selection bias

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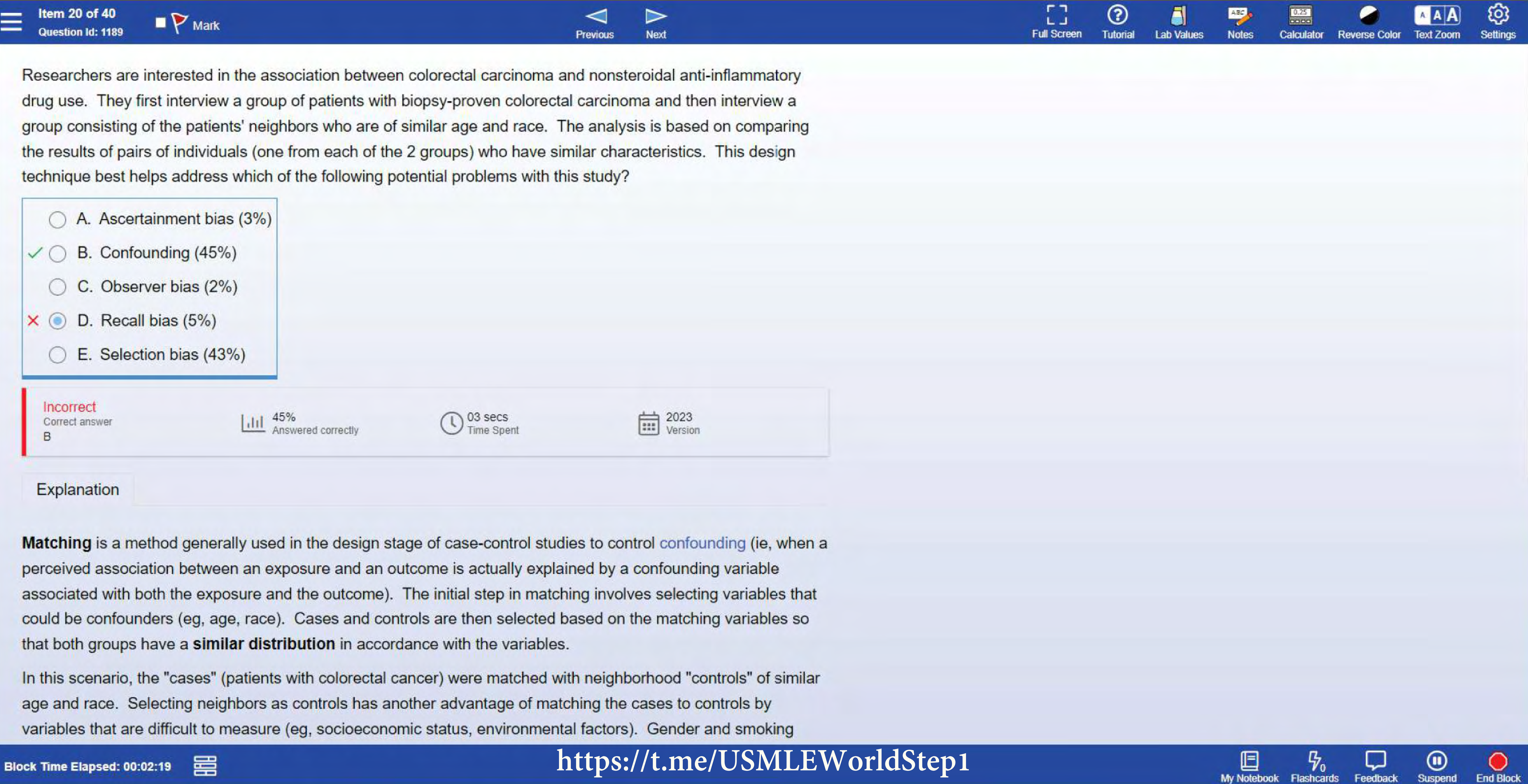
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Researchers are interested in the association between colorectal carcinoma and nonsteroidal anti-inflammatory drug use. They first interview a group of patients with biopsy-proven colorectal carcinoma and then interview a group consisting of the patients' neighbors who are of similar age and race. The analysis is based on comparing the results of pairs of individuals (one from each of the 2 groups) who have similar characteristics. This design technique best helps address which of the following potential problems with this study?

- ○ A. Ascertainment bias (3%)
- ✓ ○ B. Confounding (45%)
- ○ C. Observer bias (2%)
- ✗ ● D. Recall bias (5%)
- ○ E. Selection bias (43%)

Incorrect
Correct answer
B

45%
Answered correctly

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Explanation

Matching is a method generally used in the design stage of case-control studies to control confounding (ie, when a perceived association between an exposure and an outcome is actually explained by a confounding variable associated with both the exposure and the outcome). The initial step in matching involves selecting variables that could be confounders (eg, age, race). Cases and controls are then selected based on the matching variables so that both groups have a **similar distribution** in accordance with the variables.

In this scenario, the "cases" (patients with colorectal cancer) were matched with neighborhood "controls" of similar age and race. Selecting neighbors as controls has another advantage of matching the cases to controls by variables that are difficult to measure (eg, socioeconomic status, environmental factors). Gender and smoking

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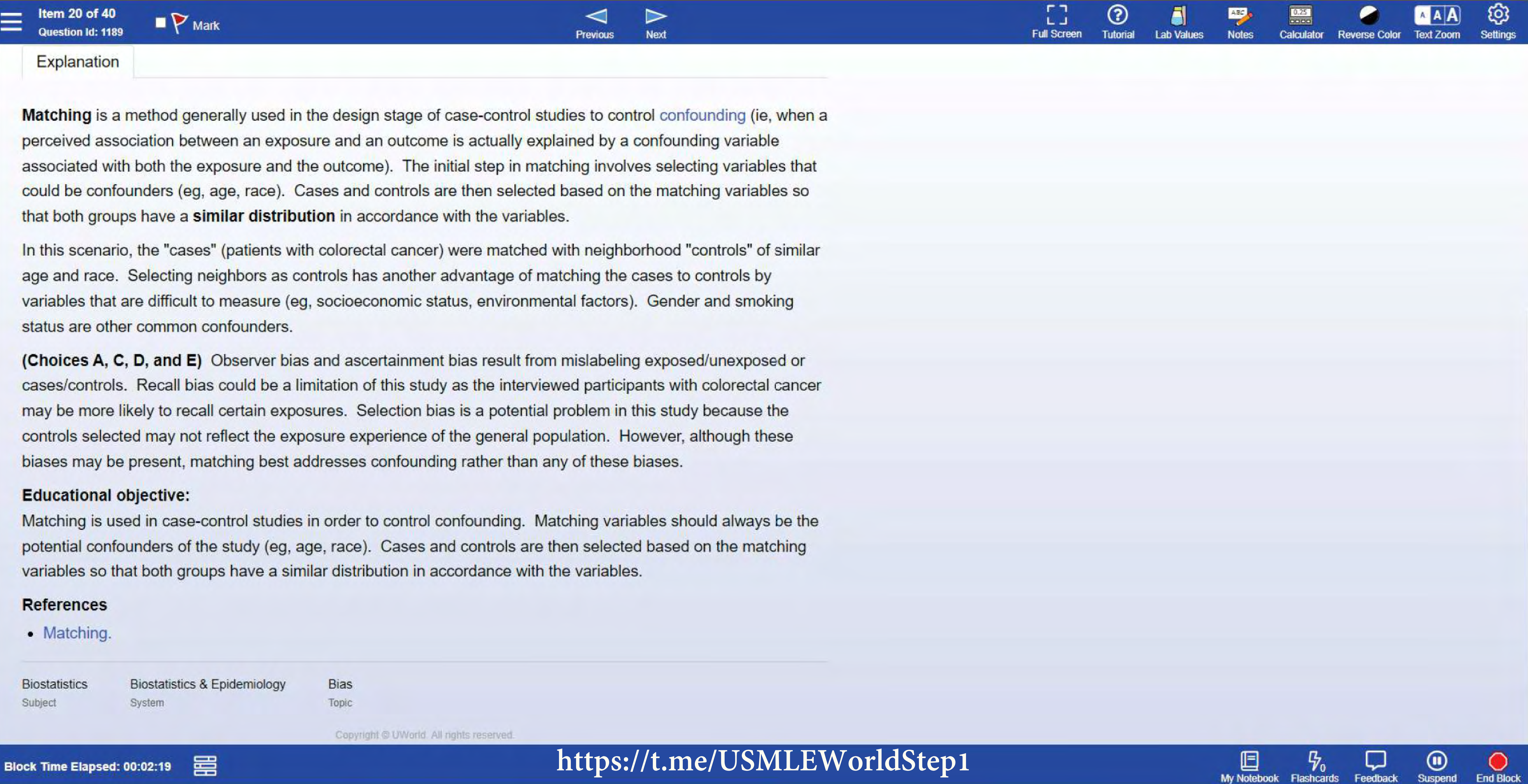
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Explanation

Matching is a method generally used in the design stage of case-control studies to control confounding (ie, when a perceived association between an exposure and an outcome is actually explained by a confounding variable associated with both the exposure and the outcome). The initial step in matching involves selecting variables that could be confounders (eg, age, race). Cases and controls are then selected based on the matching variables so that both groups have a **similar distribution** in accordance with the variables.

In this scenario, the "cases" (patients with colorectal cancer) were matched with neighborhood "controls" of similar age and race. Selecting neighbors as controls has another advantage of matching the cases to controls by variables that are difficult to measure (eg, socioeconomic status, environmental factors). Gender and smoking status are other common confounders.

(Choices A, C, D, and E) Observer bias and ascertainment bias result from mislabeling exposed/unexposed or cases/controls. Recall bias could be a limitation of this study as the interviewed participants with colorectal cancer may be more likely to recall certain exposures. Selection bias is a potential problem in this study because the controls selected may not reflect the exposure experience of the general population. However, although these biases may be present, matching best addresses confounding rather than any of these biases.

Educational objective:

Matching is used in case-control studies in order to control confounding. Matching variables should always be the potential confounders of the study (eg, age, race). Cases and controls are then selected based on the matching variables so that both groups have a similar distribution in accordance with the variables.

References

- Matching.

Biostatistics	Biostatistics & Epidemiology	Bias
Subject	System	Topic

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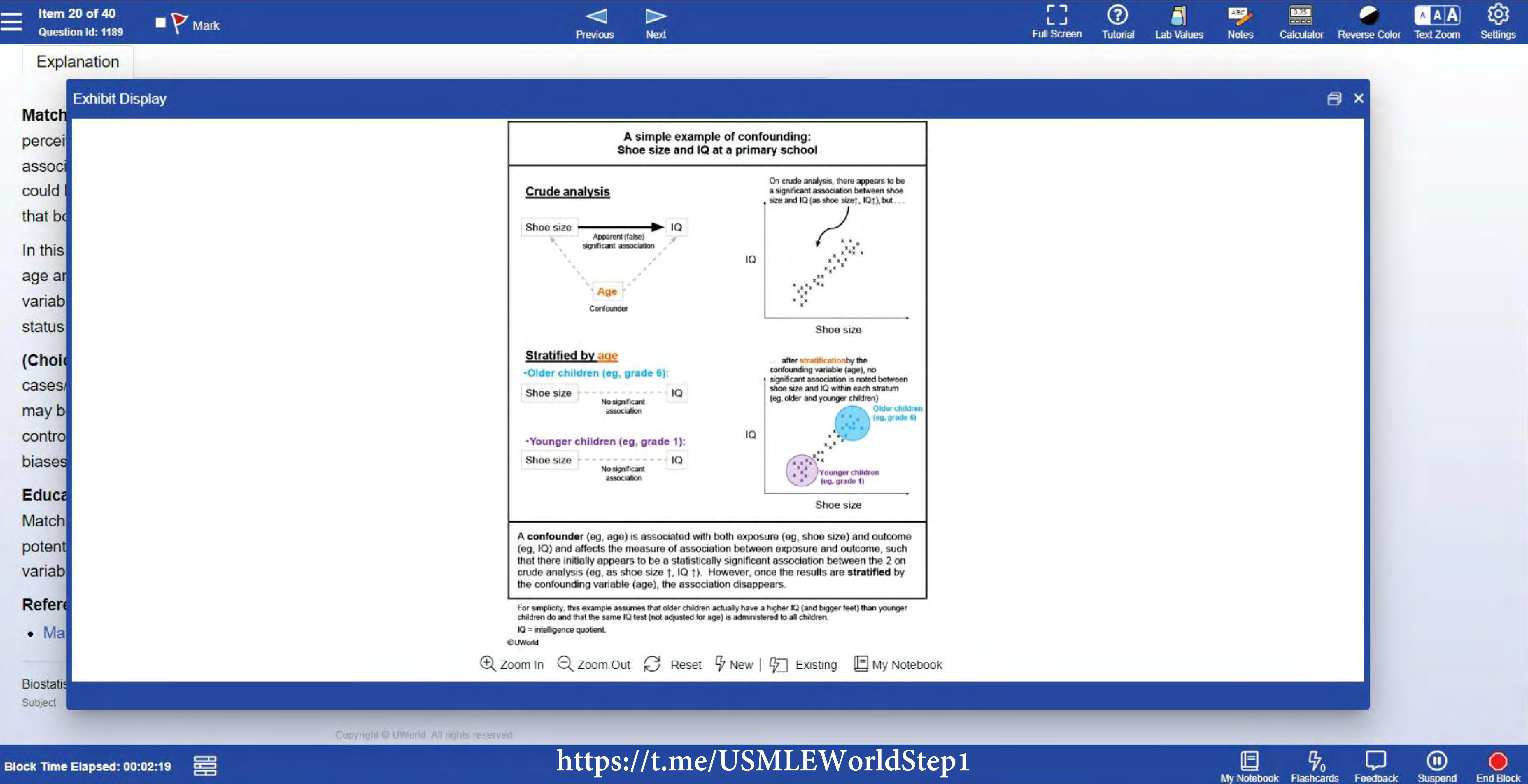
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A simple example of confounding: Shoe size and IQ at a primary school

Crude analysis

Shoe size
IQ
Apparent (false) significant association
Age
Confounder
IQ
Shoe size

On crude analysis, there appears to be a significant association between shoe size and IQ (as shoe size↑, IQ↑), but . . .

Stratified by age

•Older children (eg, grade 6):

Shoe size
IQ
No significant association

•Younger children (eg, grade 1):

Shoe size
IQ
No significant association
IQ
Older children (eg, grade 6)
Younger children (eg, grade 1)
Shoe size

. . . after stratification by the confounding variable (age), no significant association is noted between shoe size and IQ within each stratum (eg, older and younger children)

A **confounder** (eg, age) is associated with both exposure (eg, shoe size) and outcome (eg, IQ) and affects the measure of association between exposure and outcome, such that there initially appears to be a statistically significant association between the 2 on crude analysis (eg, as shoe size ↑, IQ ↑). However, once the results are **stratified** by the confounding variable (age), the association disappears.

For simplicity, this example assumes that older children actually have a higher IQ (and bigger feet) than younger children do and that the same IQ test (not adjusted for age) is administered to all children.

IQ = intelligence quotient.

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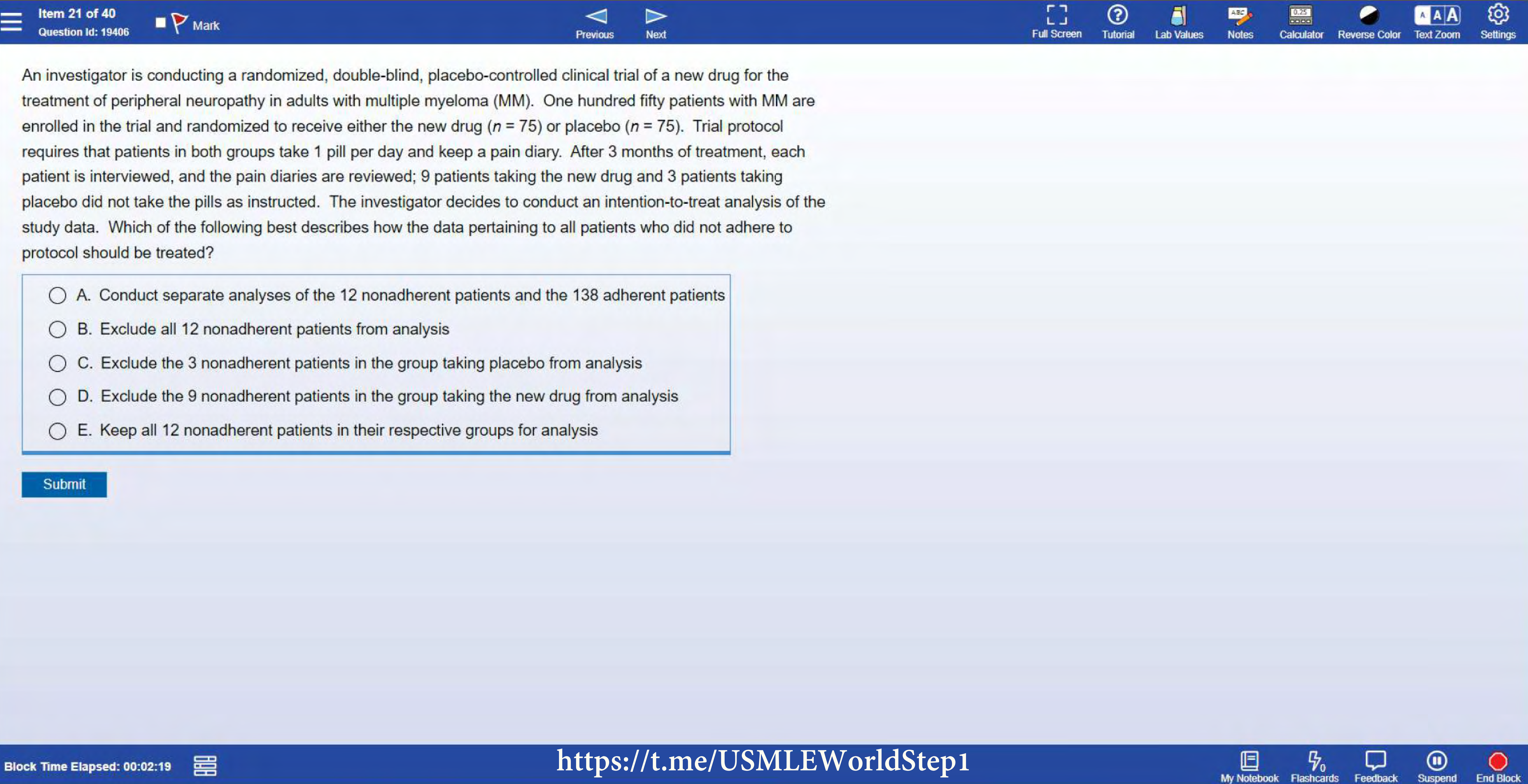

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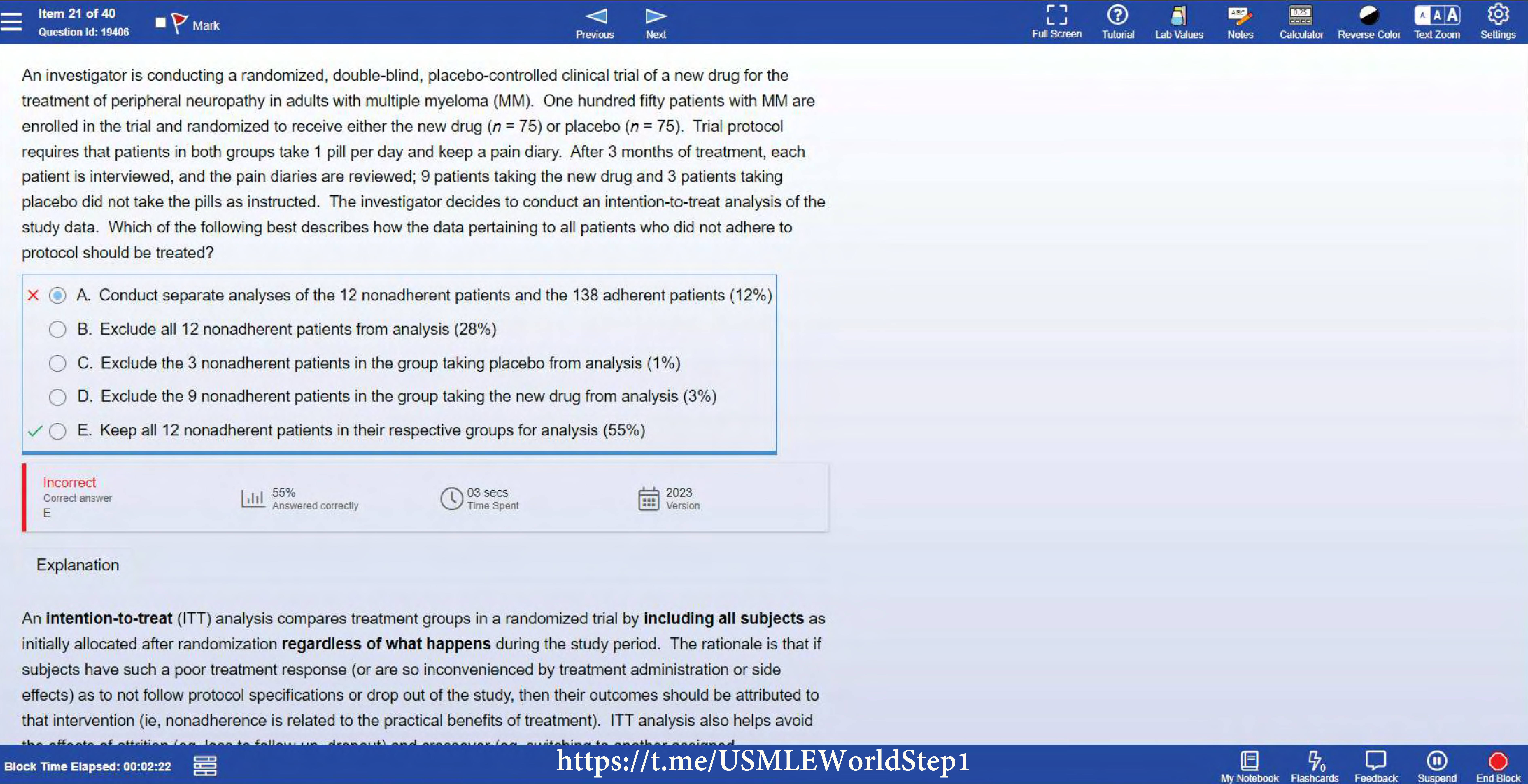
An investigator is conducting a randomized, double-blind, placebo-controlled clinical trial of a new drug for the treatment of peripheral neuropathy in adults with multiple myeloma (MM). One hundred fifty patients with MM are enrolled in the trial and randomized to receive either the new drug ($n = 75$) or placebo ($n = 75$). Trial protocol requires that patients in both groups take 1 pill per day and keep a pain diary. After 3 months of treatment, each patient is interviewed, and the pain diaries are reviewed; 9 patients taking the new drug and 3 patients taking placebo did not take the pills as instructed. The investigator decides to conduct an intention-to-treat analysis of the study data. Which of the following best describes how the data pertaining to all patients who did not adhere to protocol should be treated?

○ A. Conduct separate analyses of the 12 nonadherent patients and the 138 adherent patients
○ B. Exclude all 12 nonadherent patients from analysis
○ C. Exclude the 3 nonadherent patients in the group taking placebo from analysis
○ D. Exclude the 9 nonadherent patients in the group taking the new drug from analysis
○ E. Keep all 12 nonadherent patients in their respective groups for analysis



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- × ● A. Conduct separate analyses of the 12 nonadherent patients and the 138 adherent patients (12%)
- ○ B. Exclude all 12 nonadherent patients from analysis (28%)
- ○ C. Exclude the 3 nonadherent patients in the group taking placebo from analysis (1%)
- ○ D. Exclude the 9 nonadherent patients in the group taking the new drug from analysis (3%)
- ✓ ○ E. Keep all 12 nonadherent patients in their respective groups for analysis (55%)

Incorrect
Correct answer
E

55%
Answered correctly

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Explanation

An **intention-to-treat** (ITT) analysis compares treatment groups in a randomized trial by **including all subjects** as initially allocated after randomization **regardless of what happens** during the study period. The rationale is that if subjects have such a poor treatment response (or are so inconvenienced by treatment administration or side effects) as to not follow protocol specifications or drop out of the study, then their outcomes should be attributed to that intervention (ie, nonadherence is related to the practical benefits of treatment). ITT analysis also helps avoid the effects of attrition (eg, loss to follow-up, dropout) and crossover (eg, switching to another assigned

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Explanation

An **intention-to-treat** (ITT) analysis compares treatment groups in a randomized trial by **including all subjects** as initially allocated after randomization **regardless of what happens** during the study period. The rationale is that if subjects have such a poor treatment response (or are so inconvenienced by treatment administration or side effects) as to not follow protocol specifications or drop out of the study, then their outcomes should be attributed to that intervention (ie, nonadherence is related to the practical benefits of treatment). ITT analysis also helps avoid the effects of attrition (eg, loss to follow-up, dropout) and crossover (eg, switching to another assigned intervention), which may disrupt the benefit of randomization and introduce bias in the estimation of the effect of the intervention.

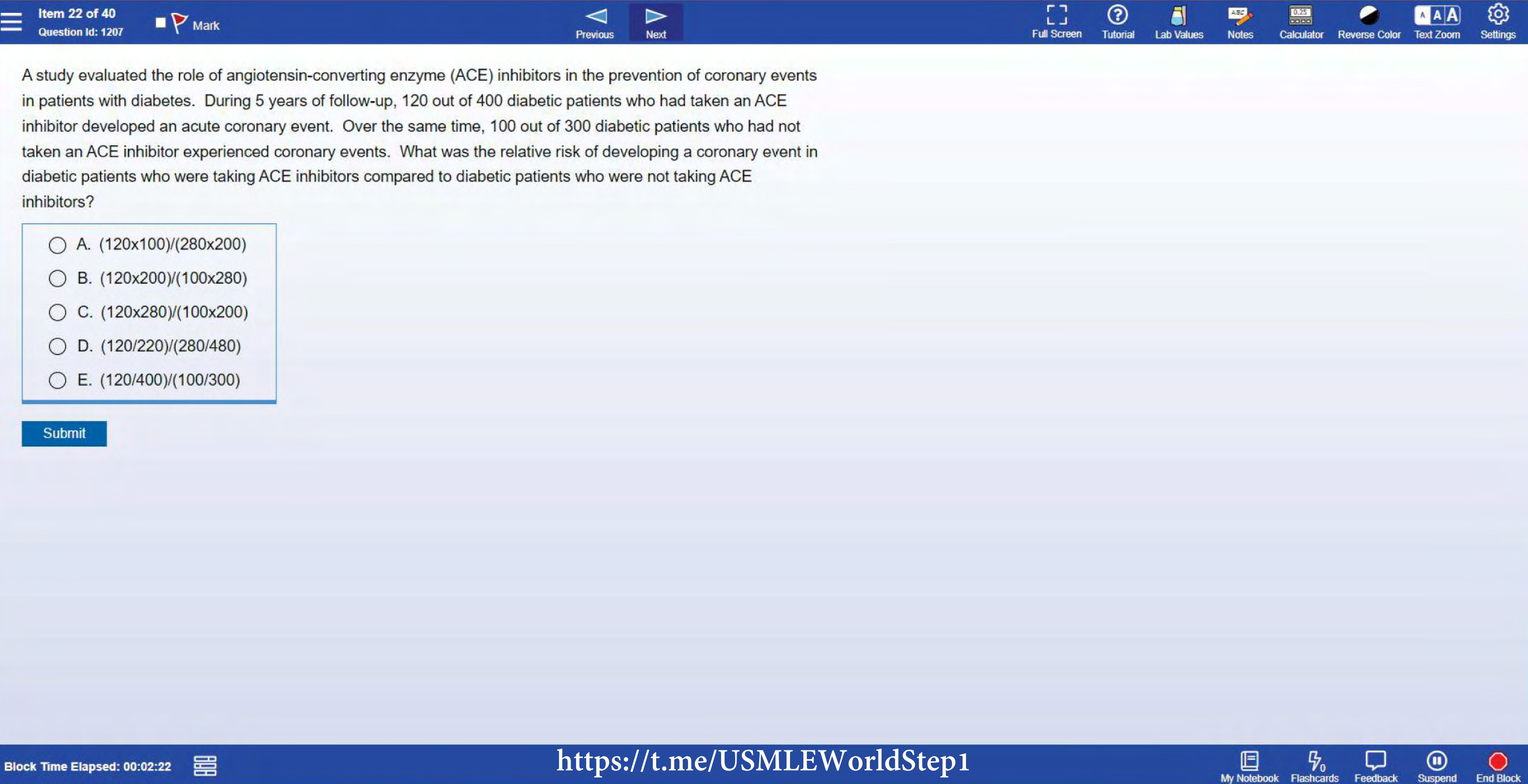
ITT analysis may lead to a more **conservative estimate** of the effect of the intervention. If attrition or crossover is significant, ITT analysis may be less likely to identify a statistically significant difference between treatments (ie, shift toward the null hypothesis). However, results will reflect the **expected effect** of the intervention in a **practical clinical setting**.

(Choices A, C, and D) In accordance with ITT analysis, the investigator in this case should keep the 12 nonadherent patients in their respective groups for analysis.

(Choice B) An analysis that includes only those patients who strictly adhered to a research protocol (ie, excluding all nonadherent patients from analysis) follows a per-protocol (PP) principle. In PP analysis, the benefit of randomization can be lost with significant subject attrition (eg, sicker subjects selectively dropping out, introducing bias). PP analysis can also overestimate the effect of the intervention in a practical clinical setting, particularly when the treatment is somehow aversive to patients.

Educational objective:

Intention-to-treat analysis includes each subject in their initial randomization group even if subjects stop the intervention or shift to a different intervention. This approach tends to provide a conservative but more valid estimate of the intervention effect in real-world scenarios (ie, clinical settings).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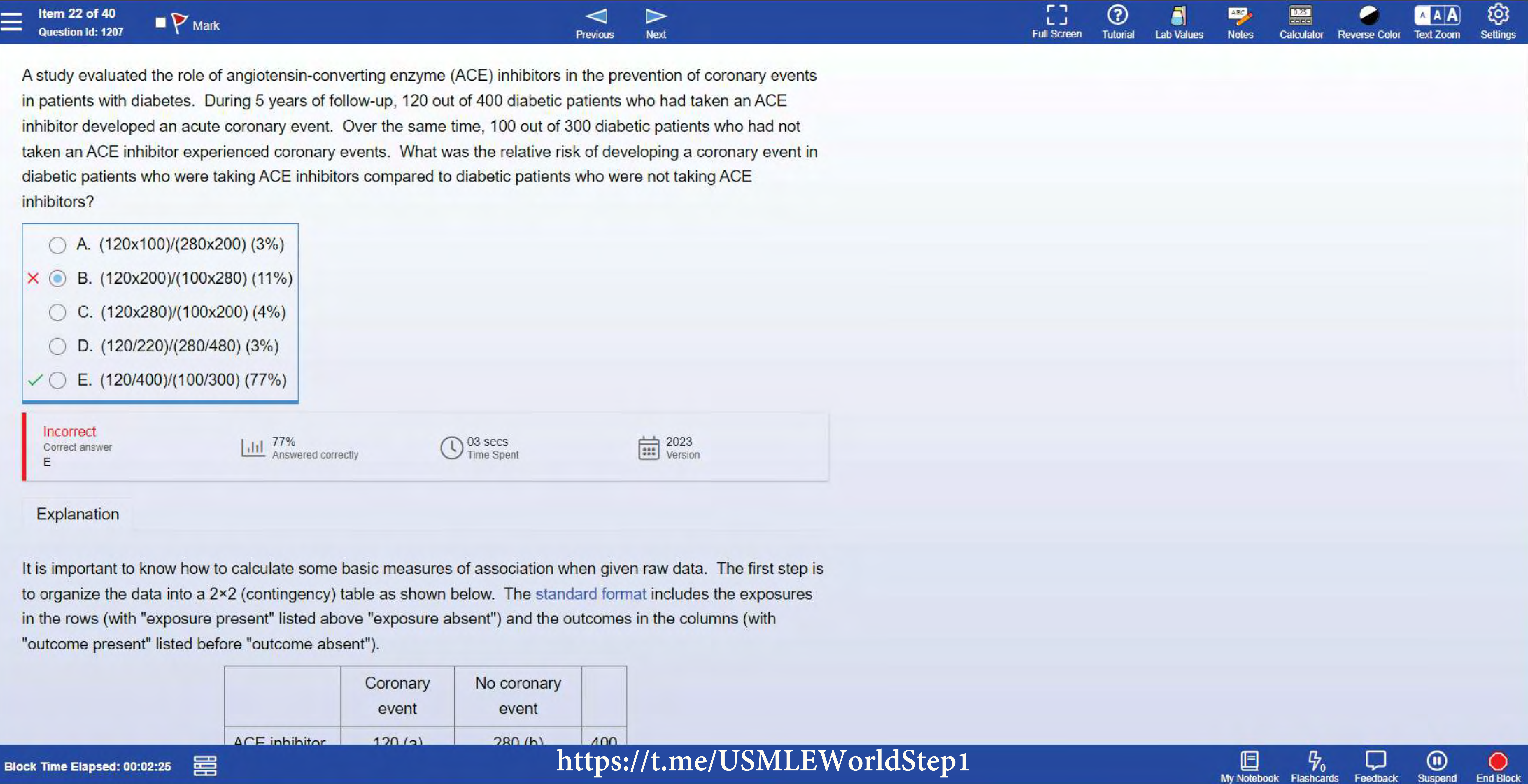
A study evaluated the role of angiotensin-converting enzyme (ACE) inhibitors in the prevention of coronary events in patients with diabetes. During 5 years of follow-up, 120 out of 400 diabetic patients who had taken an ACE inhibitor developed an acute coronary event. Over the same time, 100 out of 300 diabetic patients who had not taken an ACE inhibitor experienced coronary events. What was the relative risk of developing a coronary event in diabetic patients who were taking ACE inhibitors compared to diabetic patients who were not taking ACE inhibitors?

- ○ A. (120x100)/(280x200)
- ○ B. (120x200)/(100x280)
- ○ C. (120x280)/(100x200)
- ○ D. (120/220)/(280/480)
- ○ E. (120/400)/(100/300)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○ A. (120x100)/(280x200) (3%)
✗ ● B. (120x200)/(100x280) (11%)
○ C. (120x280)/(100x200) (4%)
○ D. (120/220)/(280/480) (3%)
✓ ○ E. (120/400)/(100/300) (77%)

Incorrect
Correct answer
E

77%
Answered correctly

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Explanation

It is important to know how to calculate some basic measures of association when given raw data. The first step is to organize the data into a 2×2 (contingency) table as shown below. The standard format includes the exposures in the rows (with "exposure present" listed above "exposure absent") and the outcomes in the columns (with "outcome present" listed before "outcome absent").

	Coronary event	No coronary event	
ACE inhibitor	120 (a)	280 (b)	400

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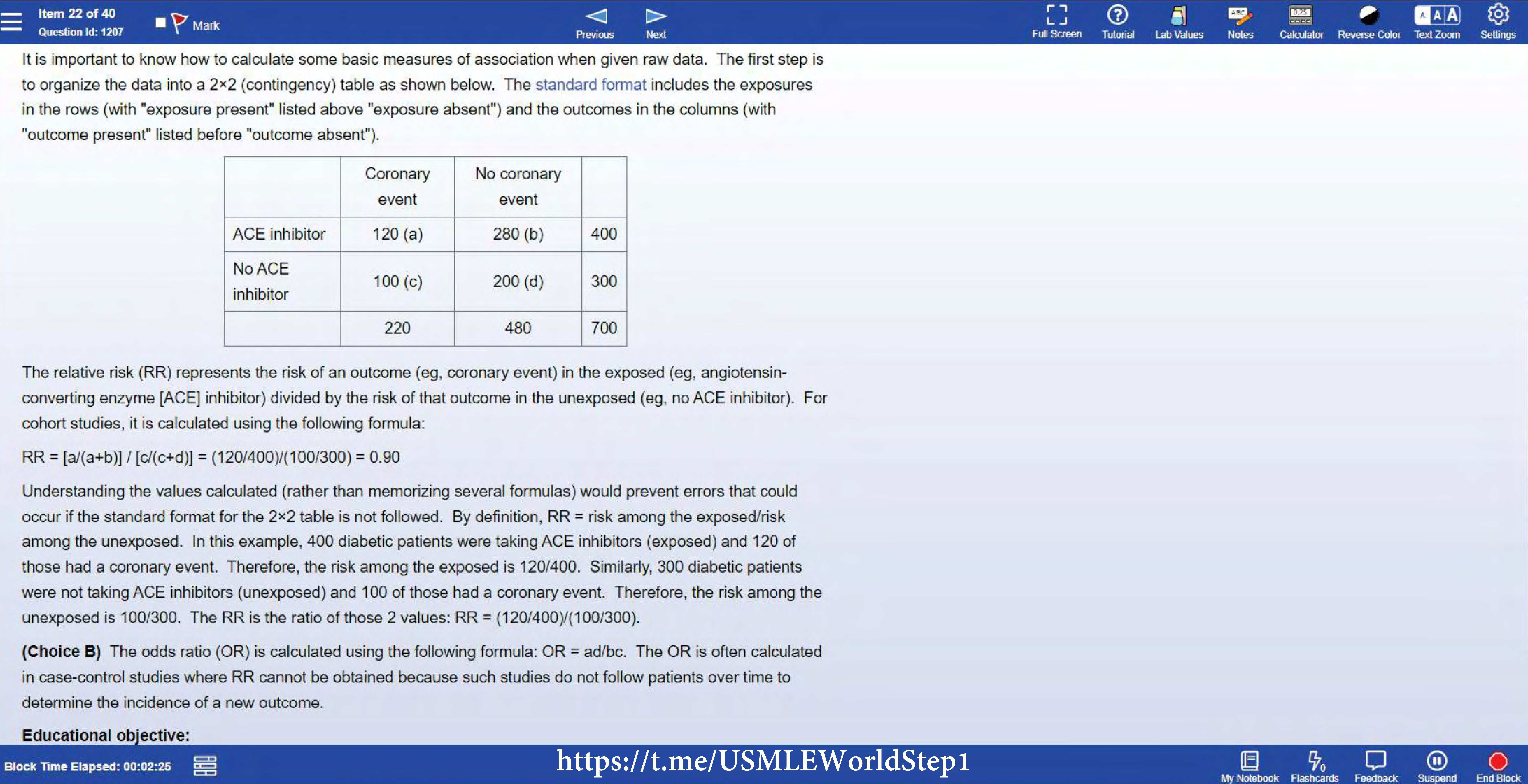
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	Coronary event	No coronary event	
ACE inhibitor	120 (a)	280 (b)	400
No ACE inhibitor	100 (c)	200 (d)	300
	220	480	700

The relative risk (RR) represents the risk of an outcome (eg, coronary event) in the exposed (eg, angiotensin-converting enzyme [ACE] inhibitor) divided by the risk of that outcome in the unexposed (eg, no ACE inhibitor). For cohort studies, it is calculated using the following formula:

$RR = [a/(a+b)] / [c/(c+d)] = (120/400)/(100/300) = 0.90$

Understanding the values calculated (rather than memorizing several formulas) would prevent errors that could occur if the standard format for the 2×2 table is not followed. By definition, RR = risk among the exposed/risk among the unexposed. In this example, 400 diabetic patients were taking ACE inhibitors (exposed) and 120 of those had a coronary event. Therefore, the risk among the exposed is 120/400. Similarly, 300 diabetic patients were not taking ACE inhibitors (unexposed) and 100 of those had a coronary event. Therefore, the risk among the unexposed is 100/300. The RR is the ratio of those 2 values: RR = (120/400)/(100/300).

(Choice B) The odds ratio (OR) is calculated using the following formula: OR = ad/bc. The OR is often calculated in case-control studies where RR cannot be obtained because such studies do not follow patients over time to determine the incidence of a new outcome.

Educational objective:

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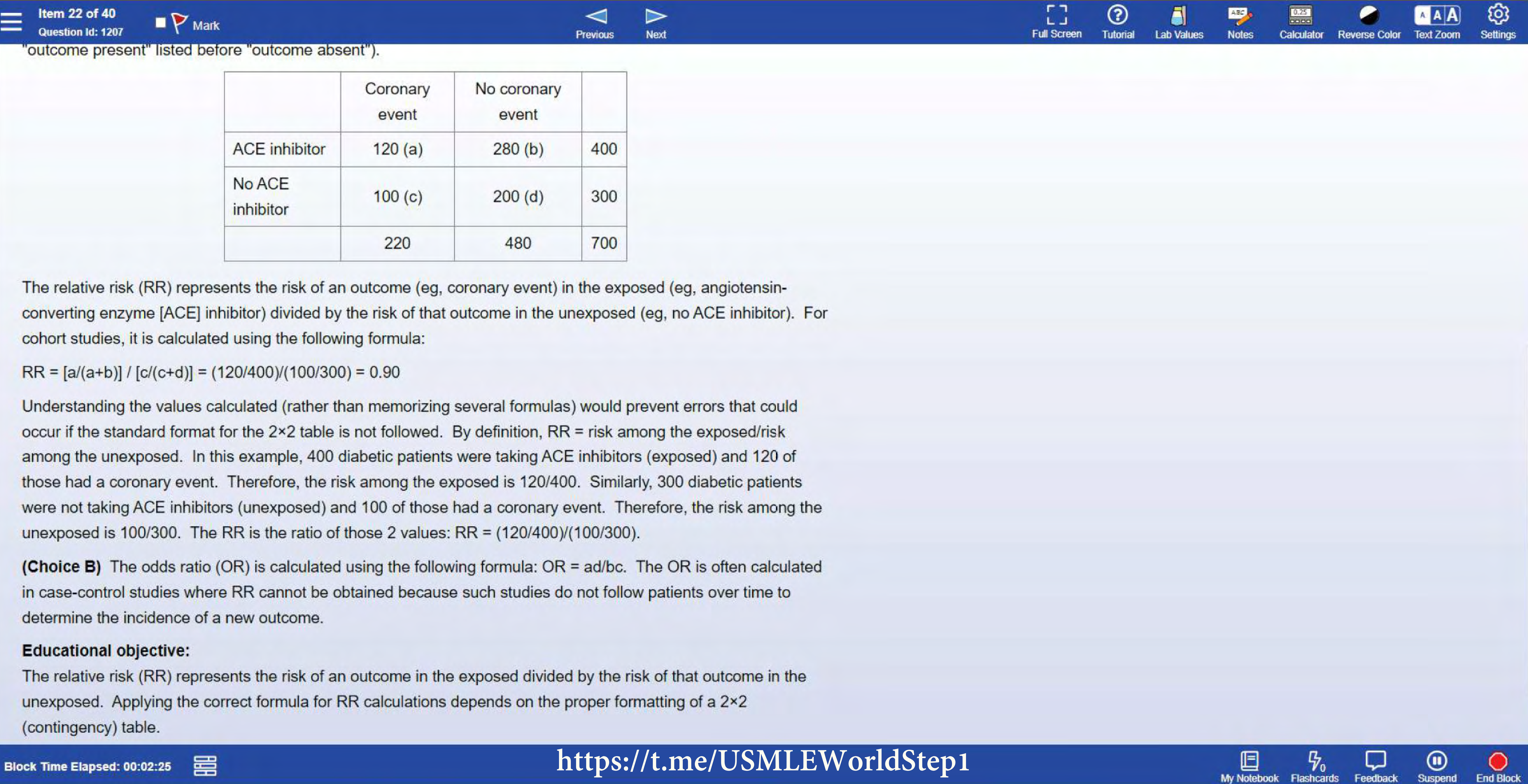
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"outcome present" listed before "outcome absent").

	Coronary event	No coronary event	
ACE inhibitor	120 (a)	280 (b)	400
No ACE inhibitor	100 (c)	200 (d)	300
	220	480	700

The relative risk (RR) represents the risk of an outcome (eg, coronary event) in the exposed (eg, angiotensin-converting enzyme [ACE] inhibitor) divided by the risk of that outcome in the unexposed (eg, no ACE inhibitor). For cohort studies, it is calculated using the following formula:

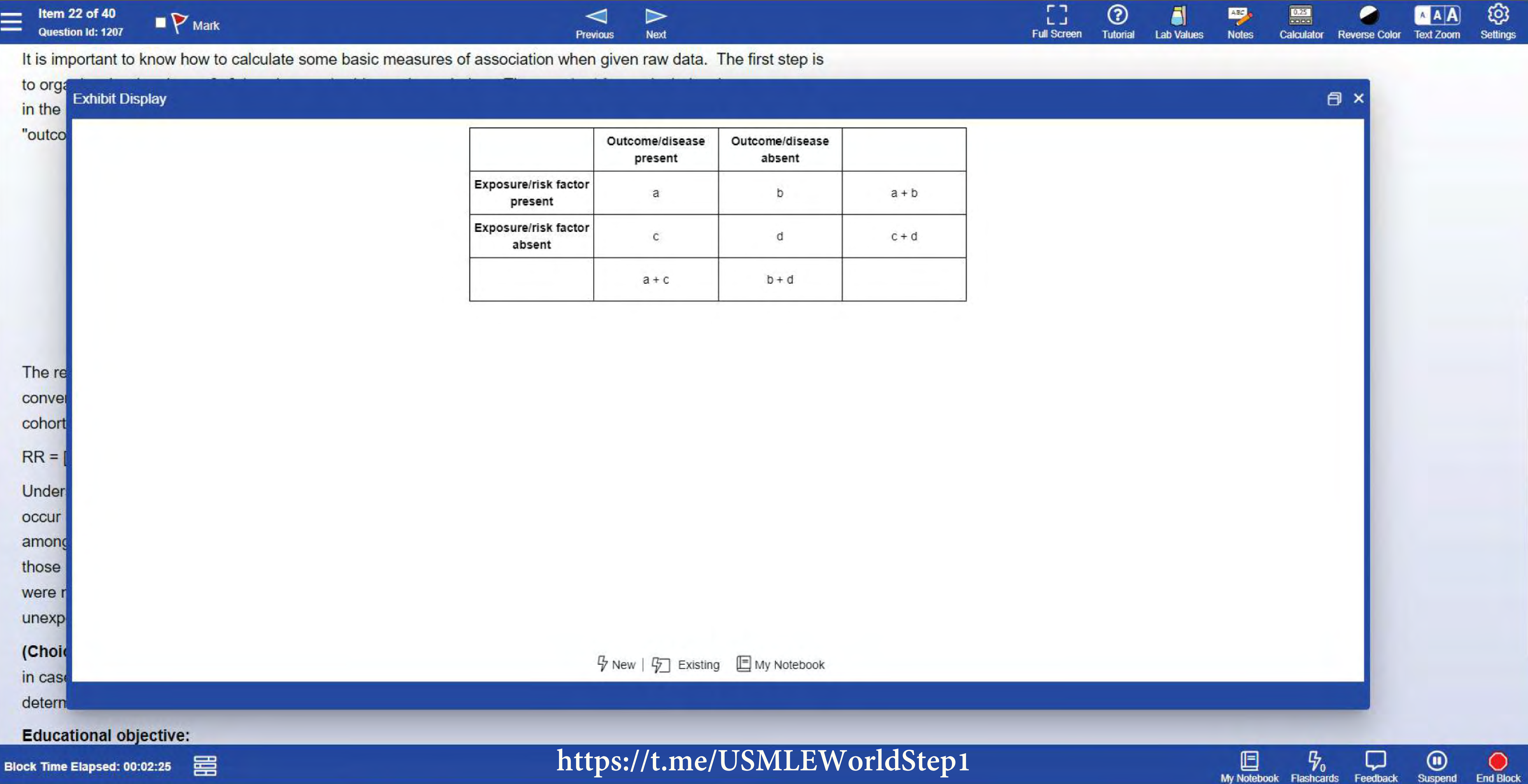
$RR = [a/(a+b)] / [c/(c+d)] = (120/400)/(100/300) = 0.90$

Understanding the values calculated (rather than memorizing several formulas) would prevent errors that could occur if the standard format for the 2×2 table is not followed. By definition, RR = risk among the exposed/risk among the unexposed. In this example, 400 diabetic patients were taking ACE inhibitors (exposed) and 120 of those had a coronary event. Therefore, the risk among the exposed is 120/400. Similarly, 300 diabetic patients were not taking ACE inhibitors (unexposed) and 100 of those had a coronary event. Therefore, the risk among the unexposed is 100/300. The RR is the ratio of those 2 values: RR = (120/400)/(100/300).

(Choice B) The odds ratio (OR) is calculated using the following formula: OR = ad/bc. The OR is often calculated in case-control studies where RR cannot be obtained because such studies do not follow patients over time to determine the incidence of a new outcome.

Educational objective:

The relative risk (RR) represents the risk of an outcome in the exposed divided by the risk of that outcome in the unexposed. Applying the correct formula for RR calculations depends on the proper formatting of a 2×2 (contingency) table.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It is important to know how to calculate some basic measures of association when given raw data. The first step is

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Educational objective:

Exhibit Display

	Outcome/disease present	**Outcome/disease absent**	
Exposure/risk factor present	a	b	a + b
Exposure/risk factor absent	c	d	c + d
	a + c	b + d	

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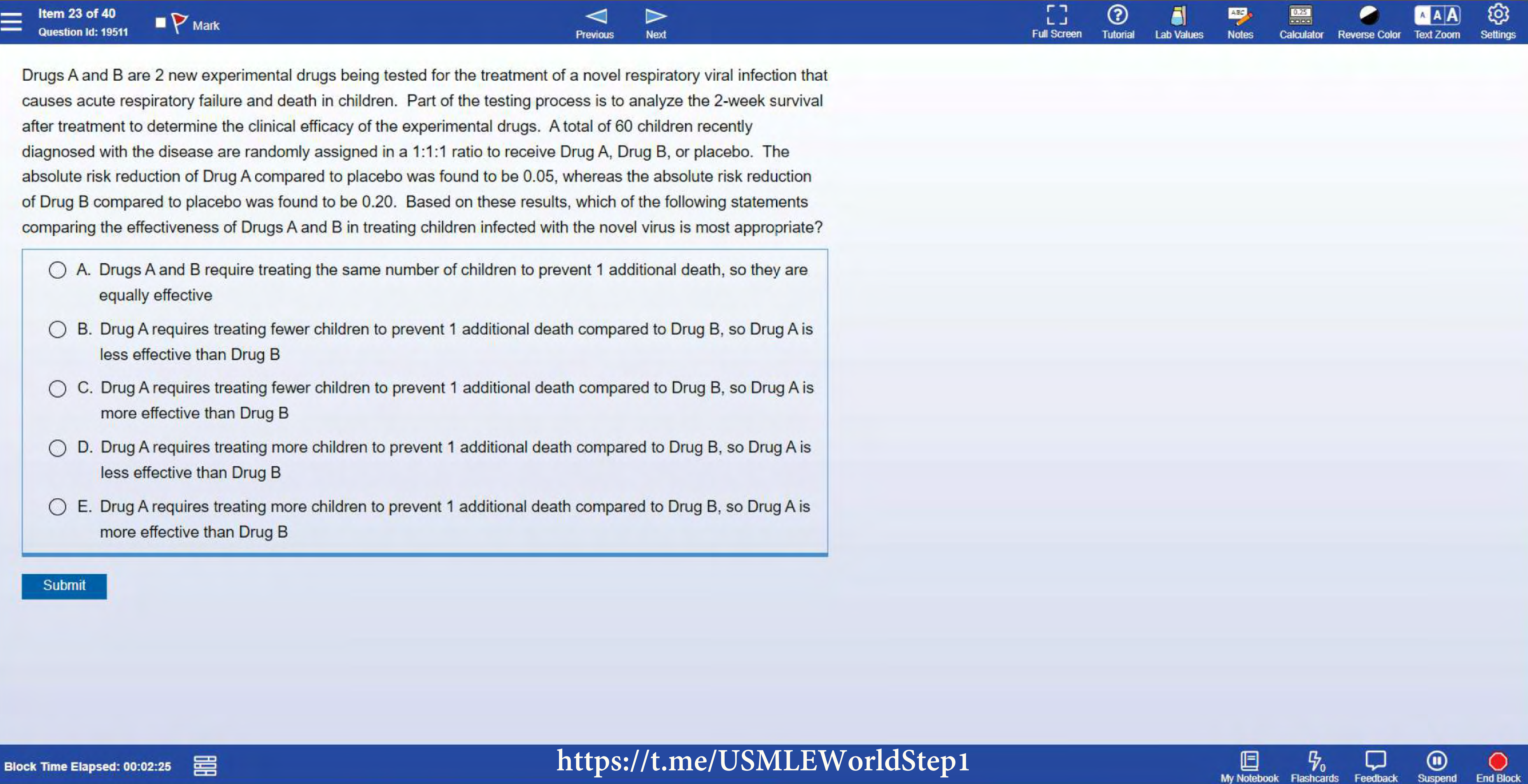
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Drugs A and B are 2 new experimental drugs being tested for the treatment of a novel respiratory viral infection that causes acute respiratory failure and death in children. Part of the testing process is to analyze the 2-week survival after treatment to determine the clinical efficacy of the experimental drugs. A total of 60 children recently diagnosed with the disease are randomly assigned in a 1:1:1 ratio to receive Drug A, Drug B, or placebo. The absolute risk reduction of Drug A compared to placebo was found to be 0.05, whereas the absolute risk reduction of Drug B compared to placebo was found to be 0.20. Based on these results, which of the following statements comparing the effectiveness of Drugs A and B in treating children infected with the novel virus is most appropriate?

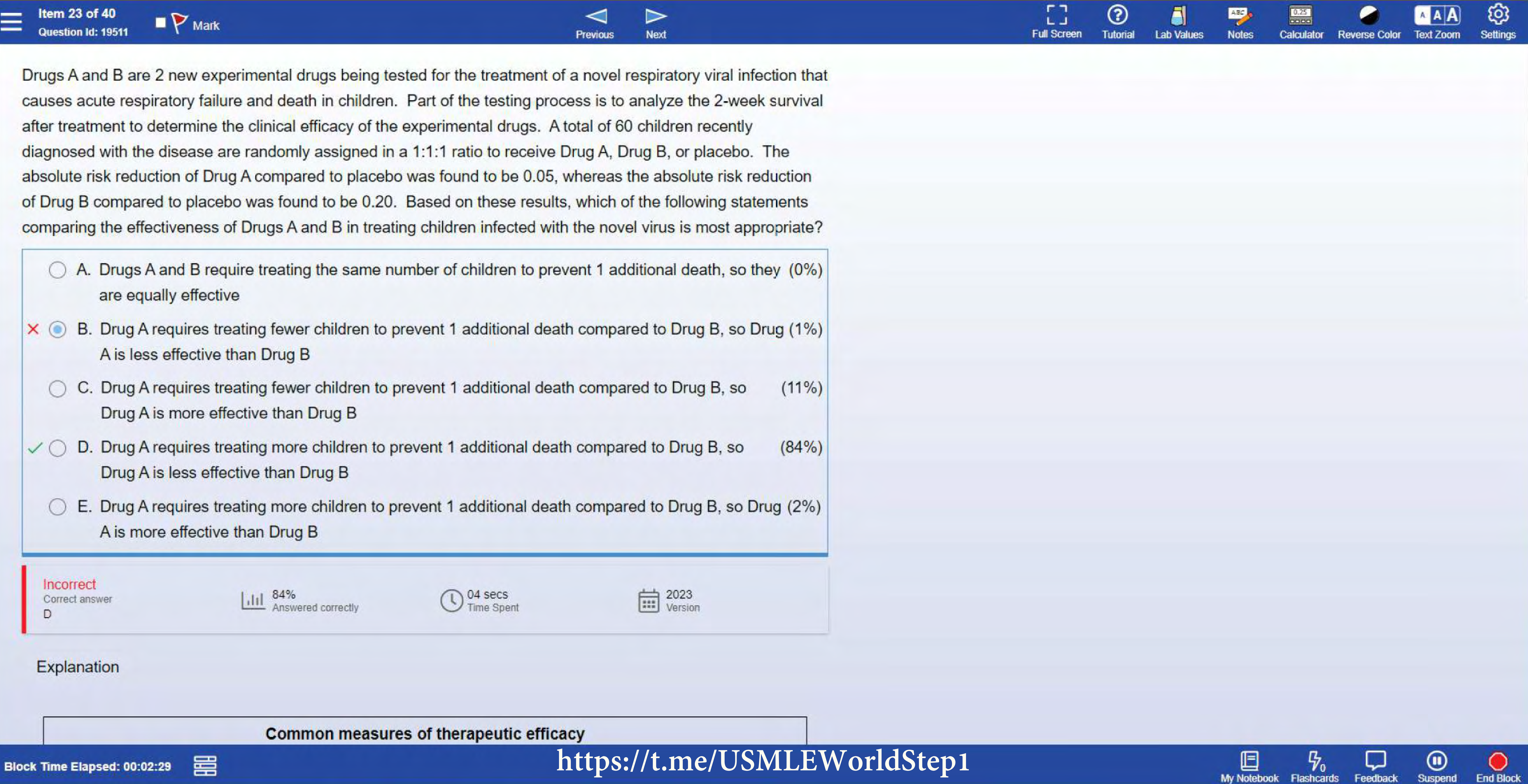
○ A. Drugs A and B require treating the same number of children to prevent 1 additional death, so they are equally effective

○ B. Drug A requires treating fewer children to prevent 1 additional death compared to Drug B, so Drug A is less effective than Drug B

○ C. Drug A requires treating fewer children to prevent 1 additional death compared to Drug B, so Drug A is more effective than Drug B

○ D. Drug A requires treating more children to prevent 1 additional death compared to Drug B, so Drug A is less effective than Drug B

○ E. Drug A requires treating more children to prevent 1 additional death compared to Drug B, so Drug A is more effective than Drug B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○ A. Drugs A and B require treating the same number of children to prevent 1 additional death, so they are equally effective (0%)

✗ ● B. Drug A requires treating fewer children to prevent 1 additional death compared to Drug B, so Drug A is less effective than Drug B (1%)

○ C. Drug A requires treating fewer children to prevent 1 additional death compared to Drug B, so Drug A is more effective than Drug B (11%)

✓ ○ D. Drug A requires treating more children to prevent 1 additional death compared to Drug B, so Drug A is less effective than Drug B (84%)

○ E. Drug A requires treating more children to prevent 1 additional death compared to Drug B, so Drug A is more effective than Drug B (2%)

Incorrect
Correct answer
D

84%
Answered correctly

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Explanation

Common measures of therapeutic efficacy

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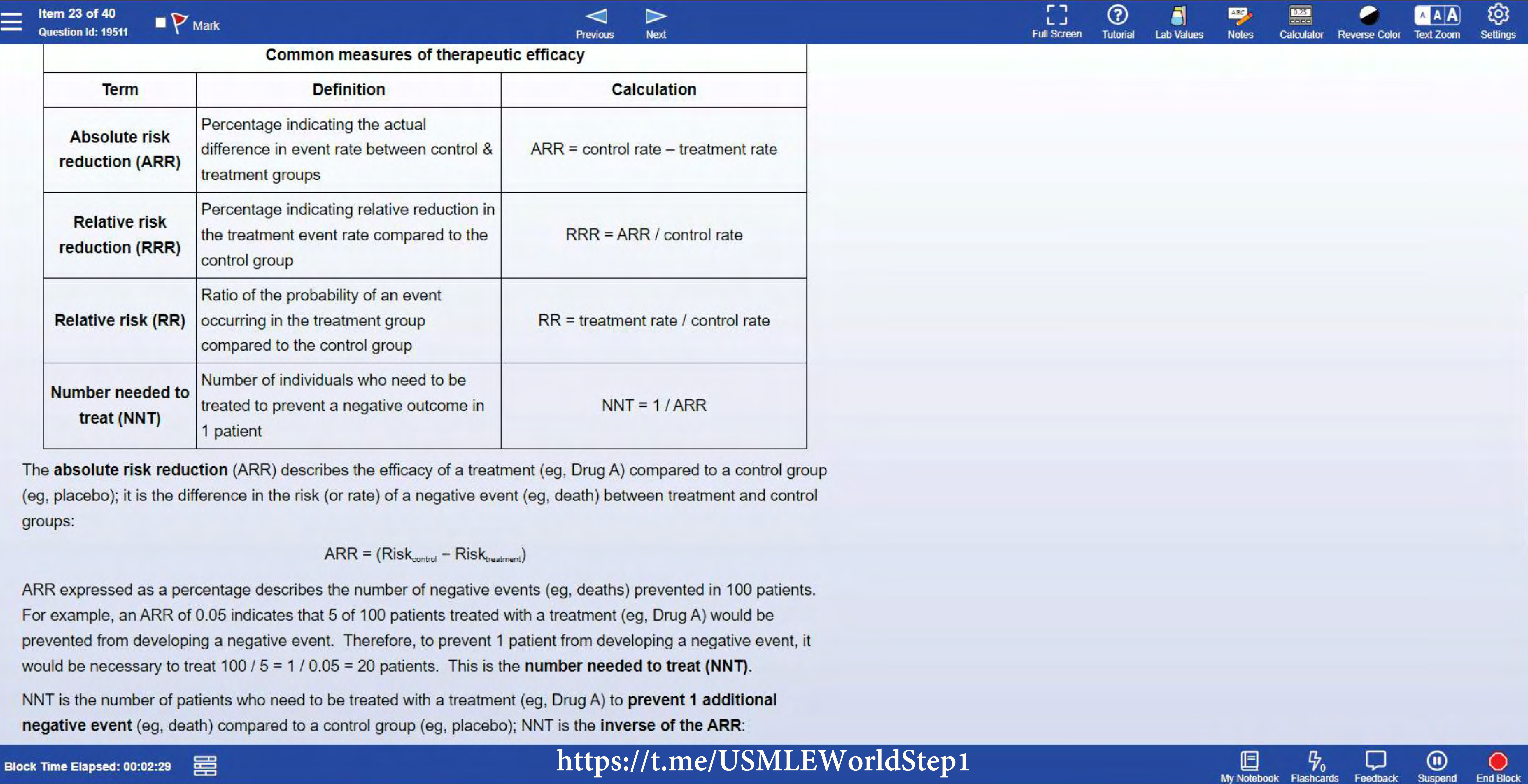
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Common measures of therapeutic efficacy

Term	Definition	Calculation
Absolute risk reduction (ARR)	Percentage indicating the actual difference in event rate between control & treatment groups	ARR = control rate – treatment rate
Relative risk reduction (RRR)	Percentage indicating relative reduction in the treatment event rate compared to the control group	RRR = ARR / control rate
Relative risk (RR)	Ratio of the probability of an event occurring in the treatment group compared to the control group	RR = treatment rate / control rate
Number needed to treat (NNT)	Number of individuals who need to be treated to prevent a negative outcome in 1 patient	NNT = 1 / ARR

The **absolute risk reduction** (ARR) describes the efficacy of a treatment (eg, Drug A) compared to a control group (eg, placebo); it is the difference in the risk (or rate) of a negative event (eg, death) between treatment and control groups:

$$\text{ARR} = (\text{Risk}_{\text{control}} - \text{Risk}_{\text{treatment}})$$

ARR expressed as a percentage describes the number of negative events (eg, deaths) prevented in 100 patients. For example, an ARR of 0.05 indicates that 5 of 100 patients treated with a treatment (eg, Drug A) would be prevented from developing a negative event. Therefore, to prevent 1 patient from developing a negative event, it would be necessary to treat 100 / 5 = 1 / 0.05 = 20 patients. This is the **number needed to treat (NNT)**.

NNT is the number of patients who need to be treated with a treatment (eg, Drug A) to **prevent 1 additional negative event** (eg, death) compared to a control group (eg, placebo); NNT is the **inverse of the ARR**:

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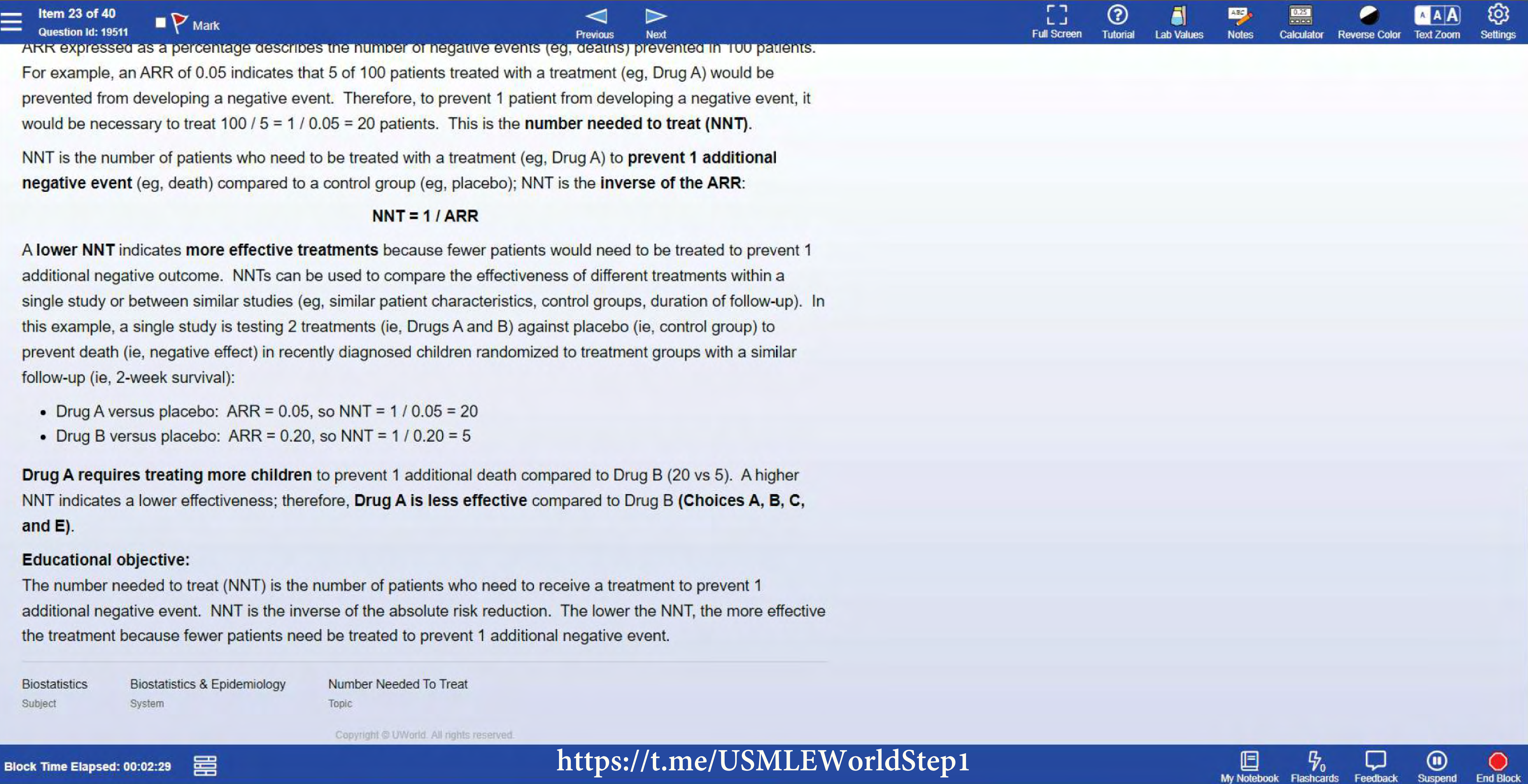

ARR expressed as a percentage describes the number of negative events (eg, deaths) prevented in 100 patients. For example, an ARR of 0.05 indicates that 5 of 100 patients treated with a treatment (eg, Drug A) would be prevented from developing a negative event. Therefore, to prevent 1 patient from developing a negative event, it would be necessary to treat 100 / 5 = 1 / 0.05 = 20 patients. This is the **number needed to treat (NNT)**.

NNT is the number of patients who need to be treated with a treatment (eg, Drug A) to **prevent 1 additional negative event** (eg, death) compared to a control group (eg, placebo); NNT is the **inverse of the ARR**:

NNT = 1 / ARR

A **lower NNT** indicates **more effective treatments** because fewer patients would need to be treated to prevent 1 additional negative outcome. NNTs can be used to compare the effectiveness of different treatments within a single study or between similar studies (eg, similar patient characteristics, control groups, duration of follow-up). In this example, a single study is testing 2 treatments (ie, Drugs A and B) against placebo (ie, control group) to prevent death (ie, negative effect) in recently diagnosed children randomized to treatment groups with a similar follow-up (ie, 2-week survival):

- Drug A versus placebo: ARR = 0.05, so NNT = 1 / 0.05 = 20
- Drug B versus placebo: ARR = 0.20, so NNT = 1 / 0.20 = 5

Drug A requires treating more children to prevent 1 additional death compared to Drug B (20 vs 5). A higher NNT indicates a lower effectiveness; therefore, **Drug A is less effective** compared to Drug B **(Choices A, B, C, and E)**.

Educational objective:
The number needed to treat (NNT) is the number of patients who need to receive a treatment to prevent 1 additional negative event. NNT is the inverse of the absolute risk reduction. The lower the NNT, the more effective the treatment because fewer patients need be treated to prevent 1 additional negative event.

Biostatistics	Biostatistics & Epidemiology	Number Needed To Treat
Subject	System	Topic

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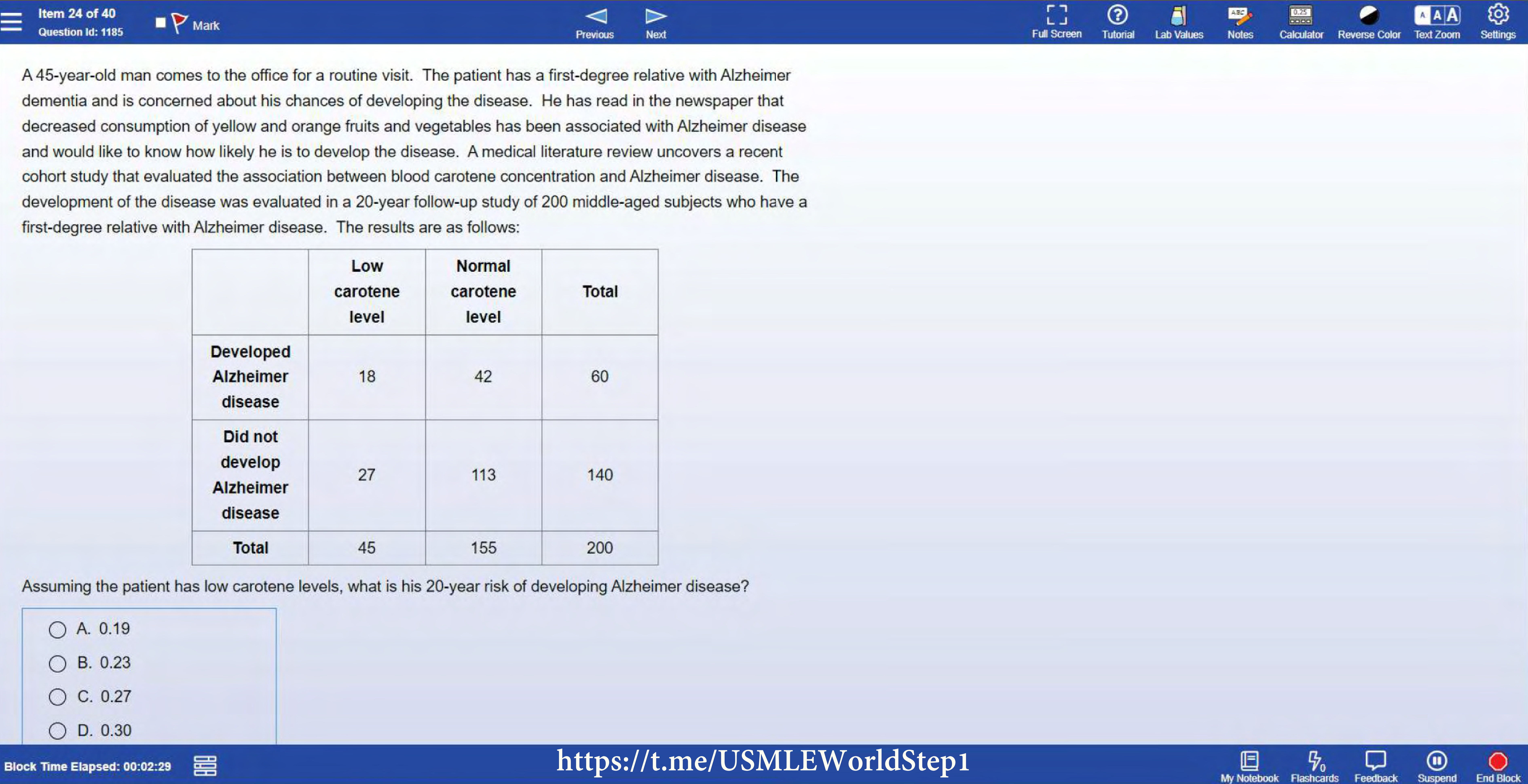
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A 45-year-old man comes to the office for a routine visit. The patient has a first-degree relative with Alzheimer dementia and is concerned about his chances of developing the disease. He has read in the newspaper that decreased consumption of yellow and orange fruits and vegetables has been associated with Alzheimer disease and would like to know how likely he is to develop the disease. A medical literature review uncovers a recent cohort study that evaluated the association between blood carotene concentration and Alzheimer disease. The development of the disease was evaluated in a 20-year follow-up study of 200 middle-aged subjects who have a first-degree relative with Alzheimer disease. The results are as follows:

	Low carotene level	**Normal carotene level**	**Total**
Developed Alzheimer disease	18	42	60
Did not develop Alzheimer disease	27	113	140
Total	45	155	200

Assuming the patient has low carotene levels, what is his 20-year risk of developing Alzheimer disease?

○ A. 0.19
○ B. 0.23
○ C. 0.27
○ D. 0.30

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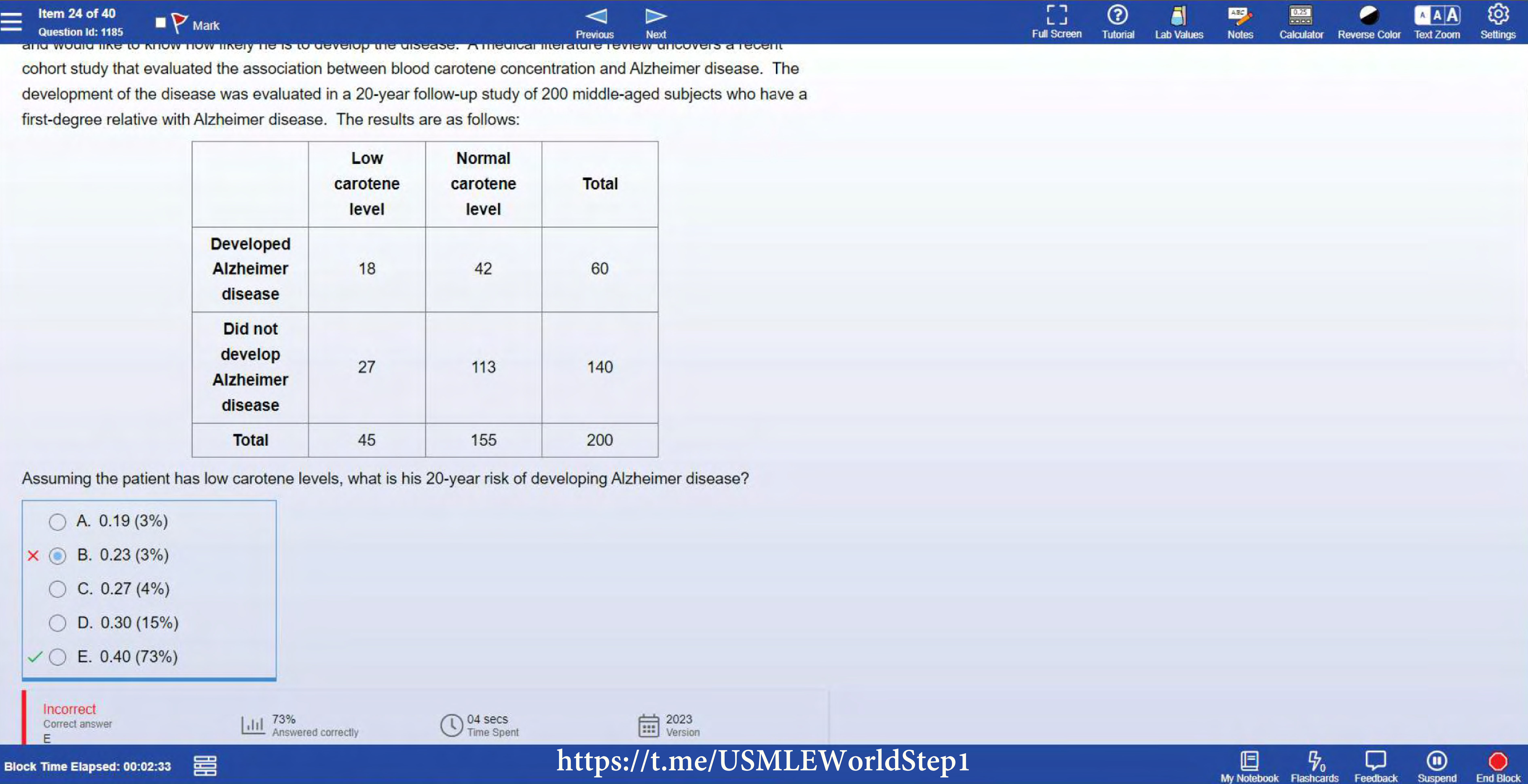
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	Low carotene level	Normal carotene level	Total
Developed Alzheimer disease	18	42	60
Did not develop Alzheimer disease	27	113	140
Total	45	155	200

Assuming the patient has low carotene levels, what is his 20-year risk of developing Alzheimer disease?

○ A. 0.19 (3%)
✗ ● B. 0.23 (3%)
○ C. 0.27 (4%)
○ D. 0.30 (15%)
✓ ○ E. 0.40 (73%)

Incorrect
Correct answer
E

73%
Answered correctly

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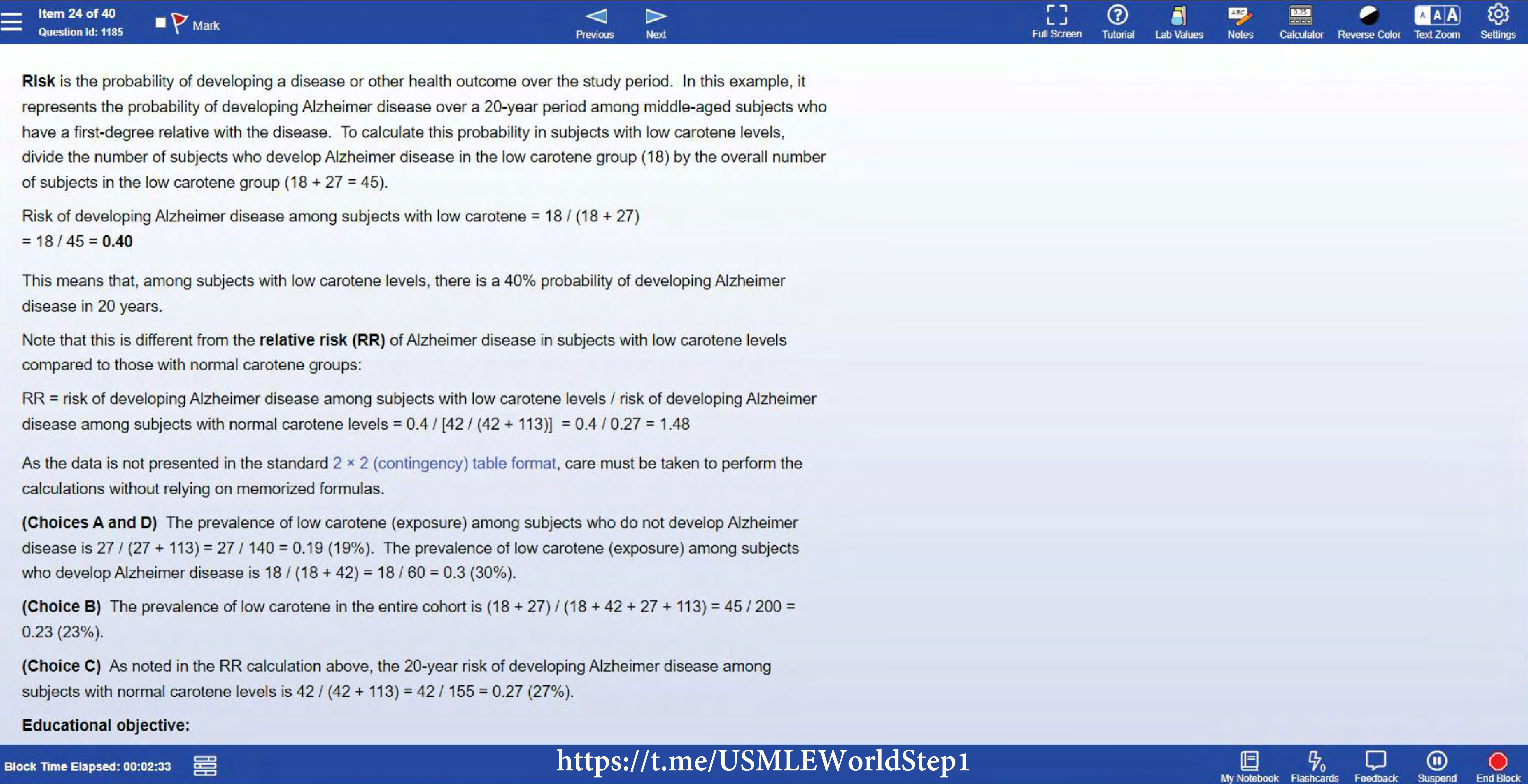
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Risk is the probability of developing a disease or other health outcome over the study period. In this example, it represents the probability of developing Alzheimer disease over a 20-year period among middle-aged subjects who have a first-degree relative with the disease. To calculate this probability in subjects with low carotene levels, divide the number of subjects who develop Alzheimer disease in the low carotene group (18) by the overall number of subjects in the low carotene group (18 + 27 = 45).

Risk of developing Alzheimer disease among subjects with low carotene = 18 / (18 + 27)
= 18 / 45 = **0.40**

This means that, among subjects with low carotene levels, there is a 40% probability of developing Alzheimer disease in 20 years.

Note that this is different from the **relative risk (RR)** of Alzheimer disease in subjects with low carotene levels compared to those with normal carotene groups:

RR = risk of developing Alzheimer disease among subjects with low carotene levels / risk of developing Alzheimer disease among subjects with normal carotene levels = 0.4 / [42 / (42 + 113)] = 0.4 / 0.27 = 1.48

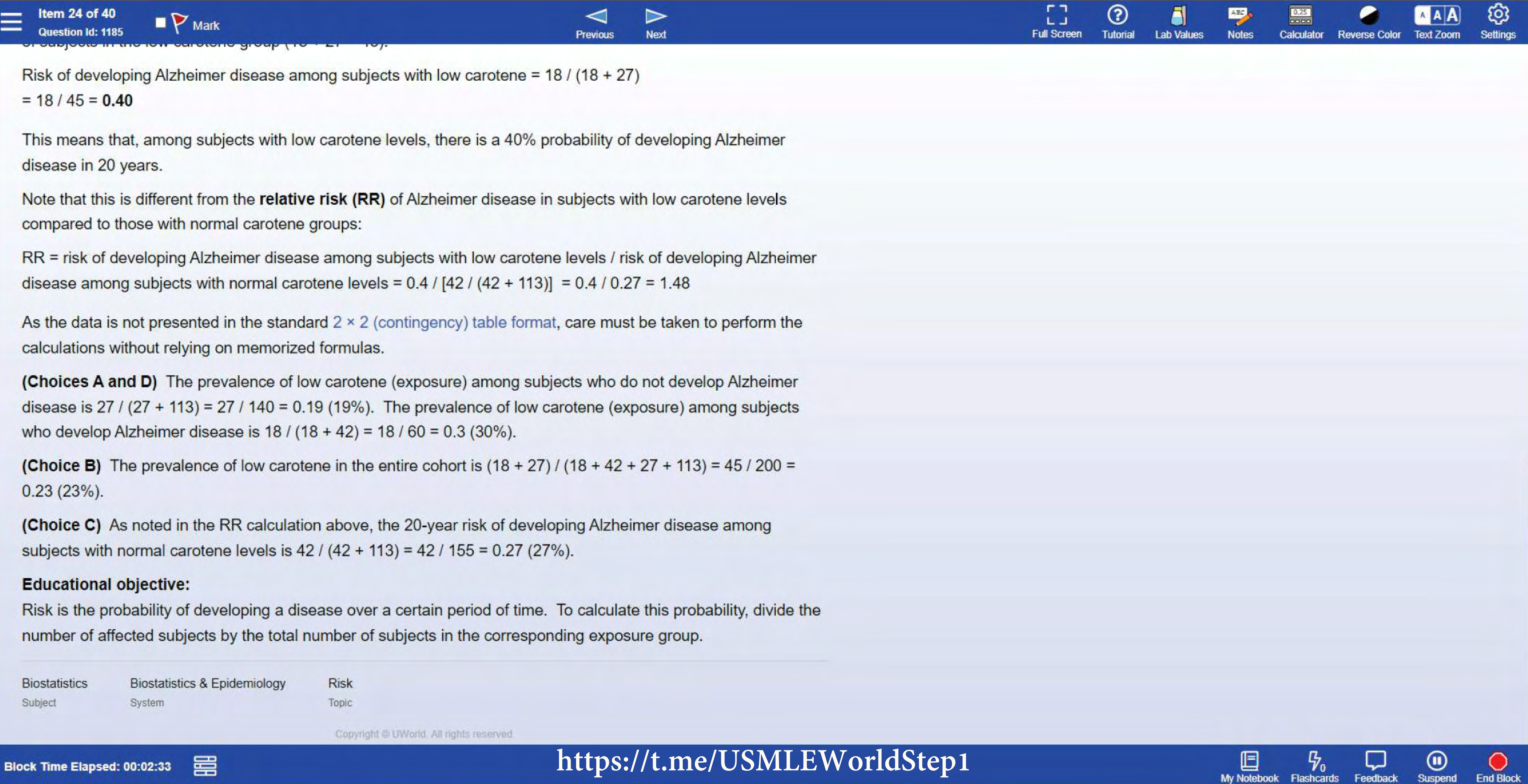
As the data is not presented in the standard 2 × 2 (contingency) table format, care must be taken to perform the calculations without relying on memorized formulas.

(Choices A and D) The prevalence of low carotene (exposure) among subjects who do not develop Alzheimer disease is 27 / (27 + 113) = 27 / 140 = 0.19 (19%). The prevalence of low carotene (exposure) among subjects who develop Alzheimer disease is 18 / (18 + 42) = 18 / 60 = 0.3 (30%).

(Choice B) The prevalence of low carotene in the entire cohort is (18 + 27) / (18 + 42 + 27 + 113) = 45 / 200 = 0.23 (23%).

(Choice C) As noted in the RR calculation above, the 20-year risk of developing Alzheimer disease among subjects with normal carotene levels is 42 / (42 + 113) = 42 / 155 = 0.27 (27%).

Educational objective: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Note that this is different from the **relative risk (RR)** of Alzheimer disease in subjects with low carotene levels compared to those with normal carotene groups:

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(Choice B) The prevalence of low carotene in the entire cohort is (18 + 27) / (18 + 42 + 27 + 113) = 45 / 200 = 0.23 (23%).

(Choice C) As noted in the RR calculation above, the 20-year risk of developing Alzheimer disease among subjects with normal carotene levels is 42 / (42 + 113) = 42 / 155 = 0.27 (27%).

Educational objective:
Risk is the probability of developing a disease over a certain period of time. To calculate this probability, divide the number of affected subjects by the total number of subjects in the corresponding exposure group.

Biostatistics	Biostatistics & Epidemiology	Risk
Subject	System	Topic

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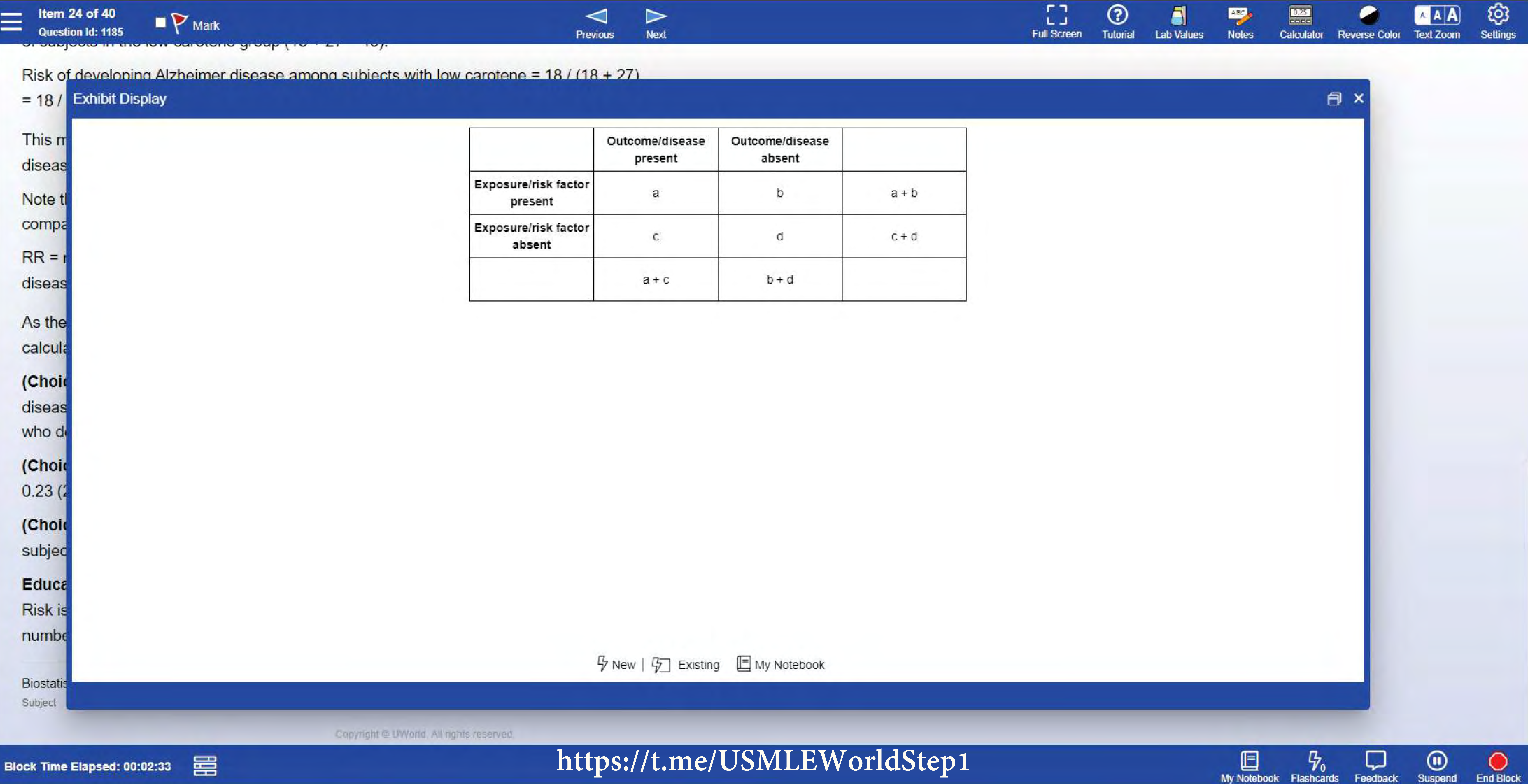
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Risk of developing Alzheimer disease among subjects with low carotene = 18 / (18 + 27)

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	Outcome/disease present	**Outcome/disease absent**	
Exposure/risk factor present	a	b	a + b
Exposure/risk factor absent	c	d	c + d
	a + c	b + d	

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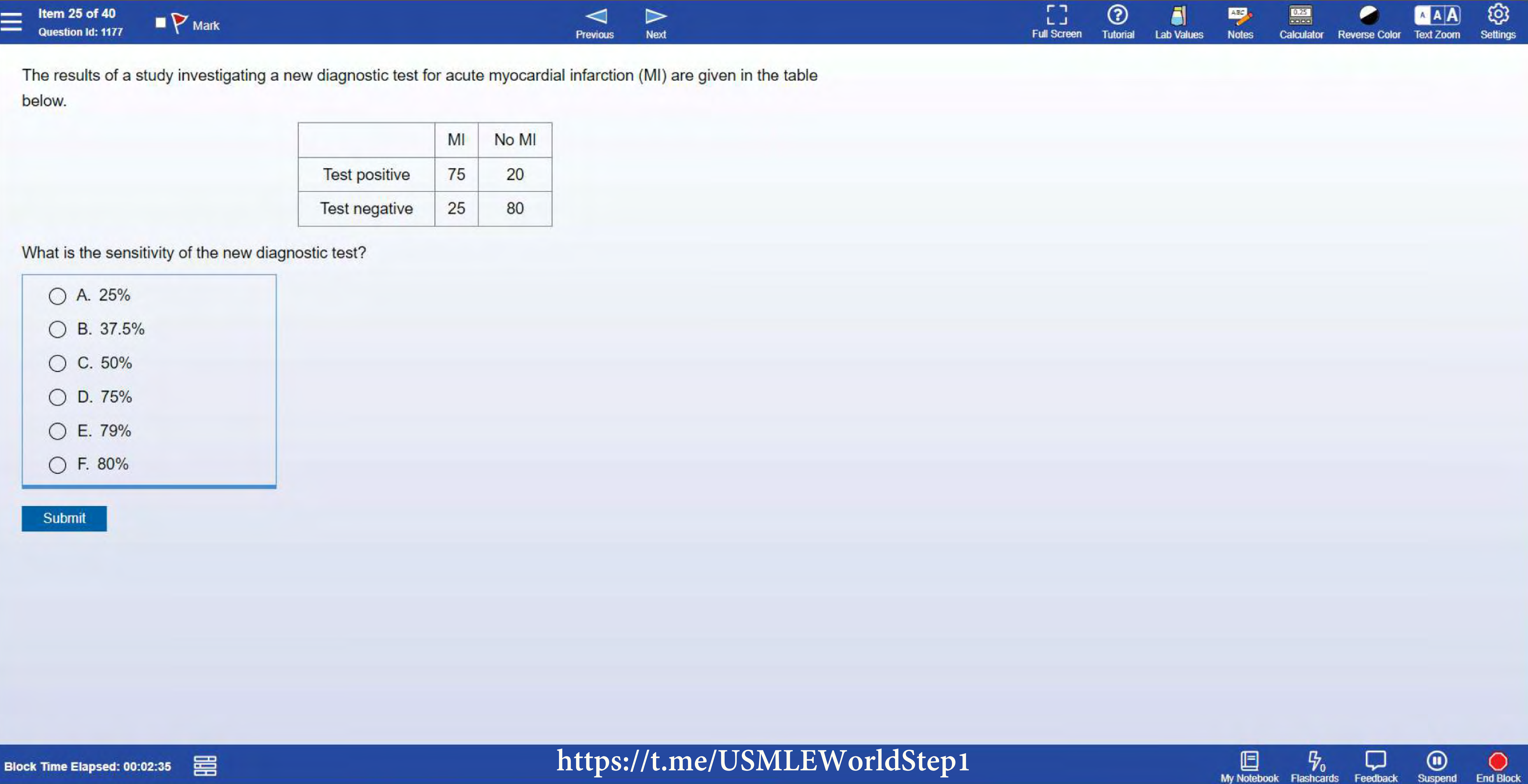
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The results of a study investigating a new diagnostic test for acute myocardial infarction (MI) are given in the table below.

	MI	No MI
Test positive	75	20
Test negative	25	80

What is the sensitivity of the new diagnostic test?

○ A. 25%
○ B. 37.5%
○ C. 50%
○ D. 75%
○ E. 79%
○ F. 80%

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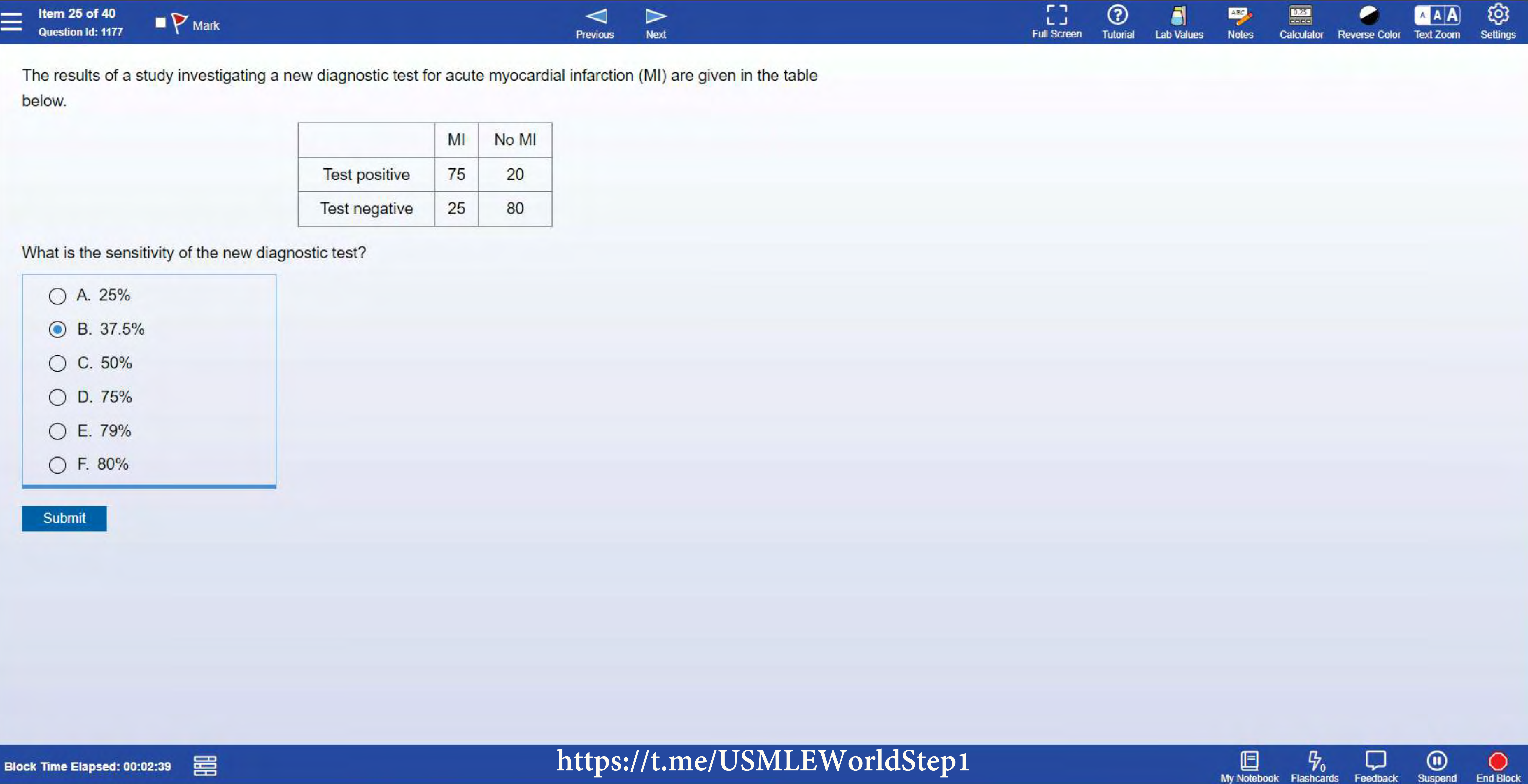
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	MI	No MI
Test positive	75	20
Test negative	25	80

What is the sensitivity of the new diagnostic test?

- ○ A. 25%
- ● B. 37.5%
- ○ C. 50%
- ○ D. 75%
- ○ E. 79%
- ○ F. 80%

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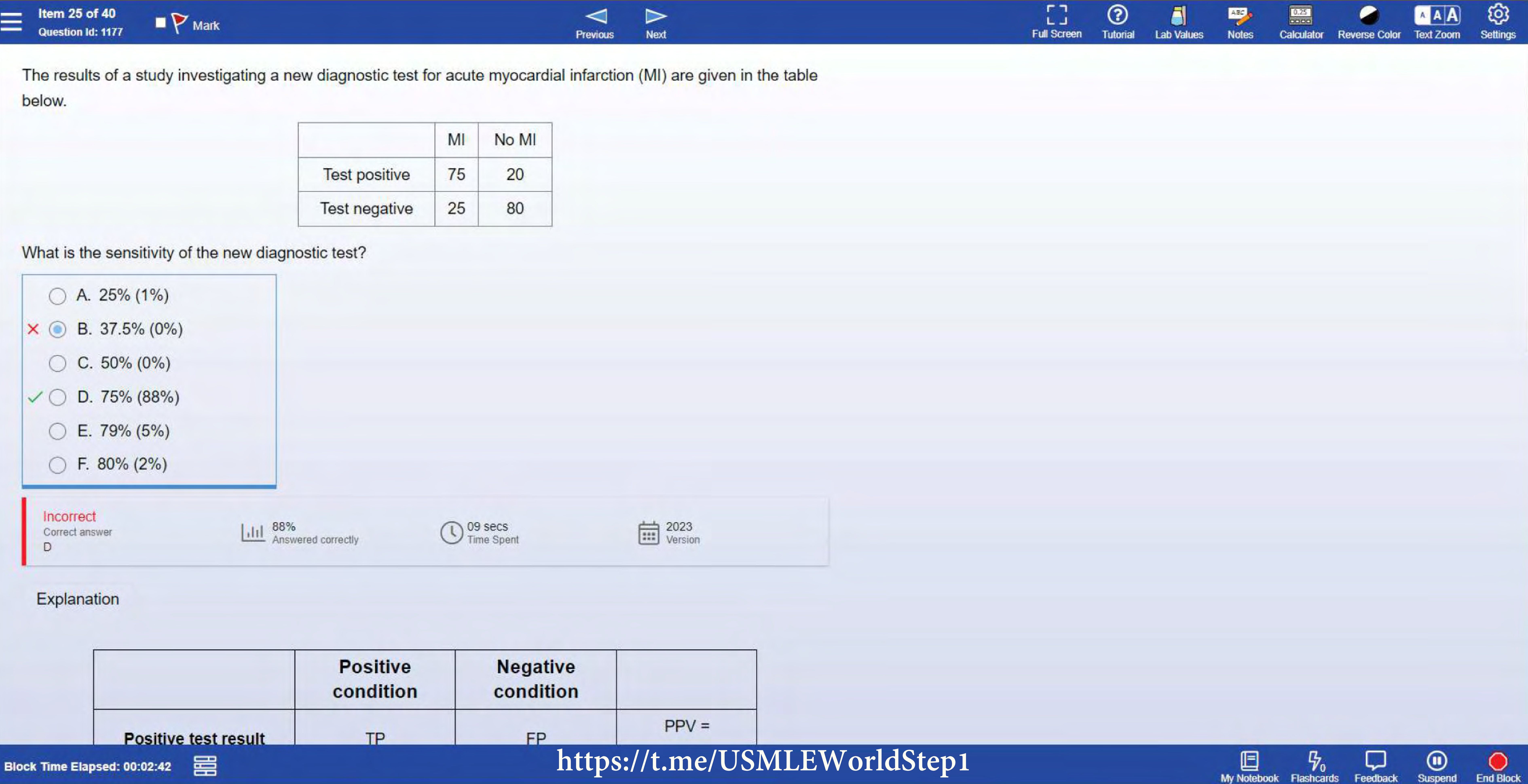
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The results of a study investigating a new diagnostic test for acute myocardial infarction (MI) are given in the table below.

	MI	No MI
Test positive	75	20
Test negative	25	80

What is the sensitivity of the new diagnostic test?

○ A. 25% (1%)
✗ ● B. 37.5% (0%)
○ C. 50% (0%)
✓ ○ D. 75% (88%)
○ E. 79% (5%)
○ F. 80% (2%)

Incorrect
Correct answer
D

88%
Answered correctly

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Explanation

	Positive condition	Negative condition	
Positive test result	TP	FP	PPV =

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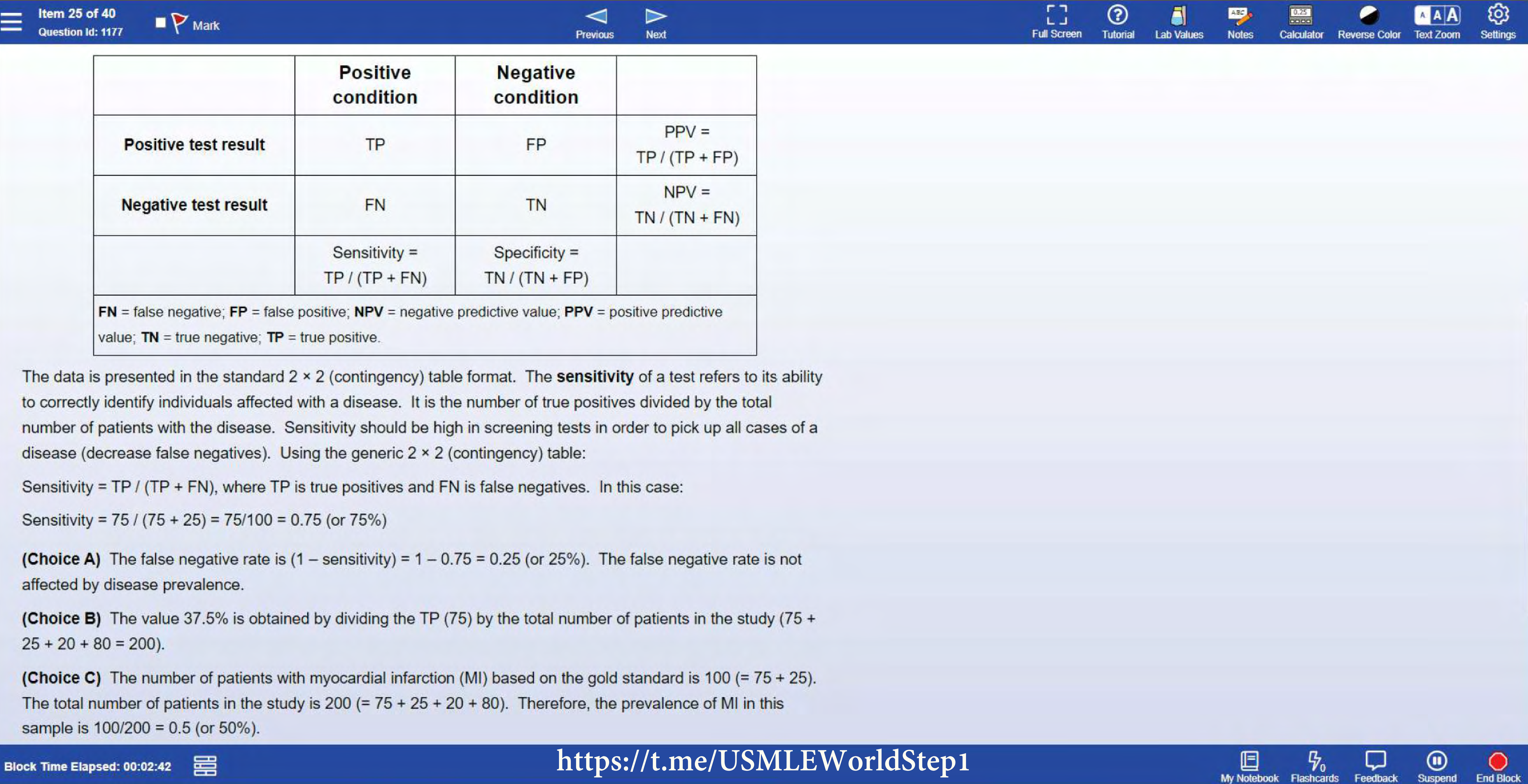
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	Positive condition	**Negative condition**	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

The data is presented in the standard 2 × 2 (contingency) table format. The **sensitivity** of a test refers to its ability to correctly identify individuals affected with a disease. It is the number of true positives divided by the total number of patients with the disease. Sensitivity should be high in screening tests in order to pick up all cases of a disease (decrease false negatives). Using the generic 2 × 2 (contingency) table:

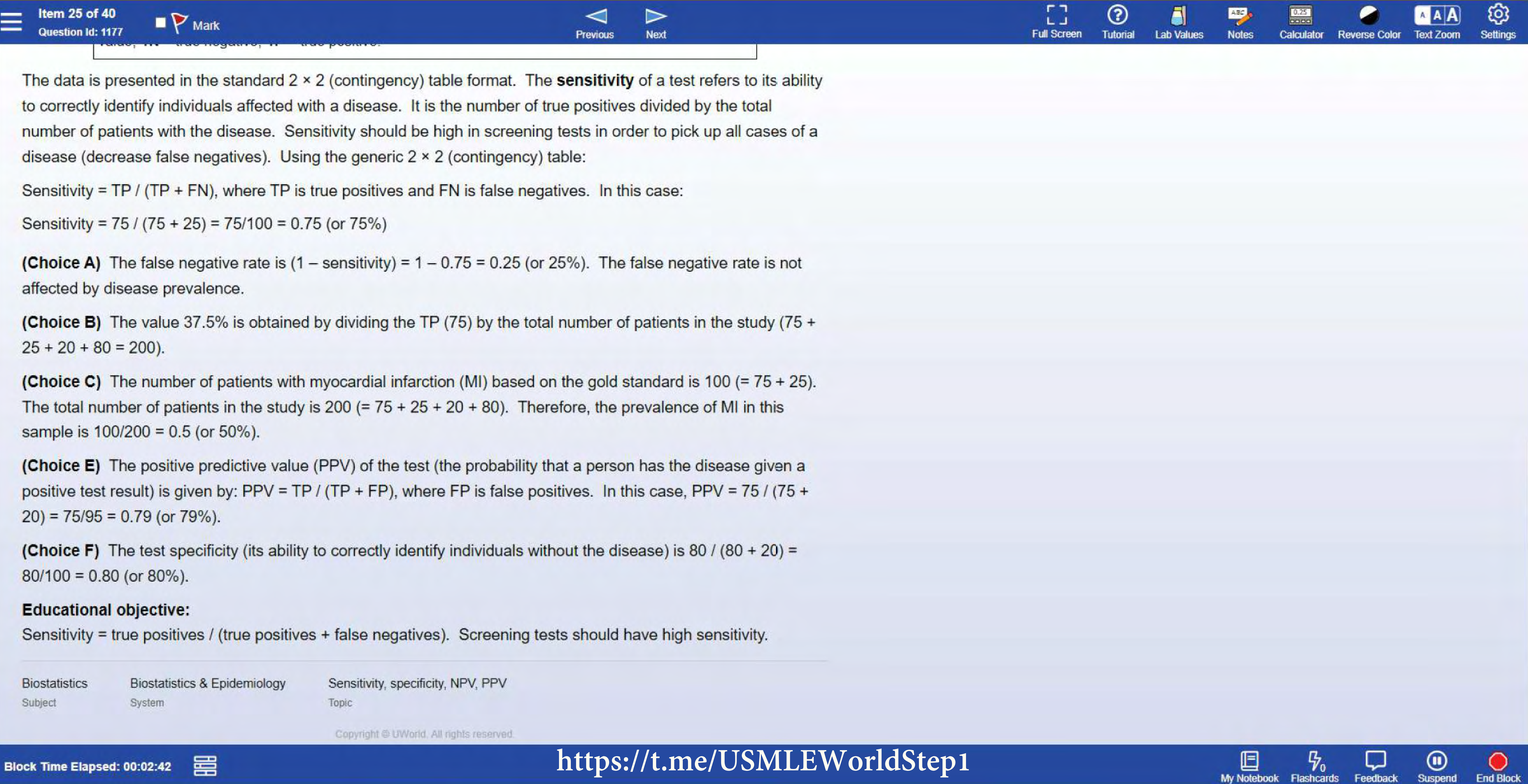
Sensitivity = TP / (TP + FN), where TP is true positives and FN is false negatives. In this case:

Sensitivity = 75 / (75 + 25) = 75/100 = 0.75 (or 75%)

(Choice A) The false negative rate is (1 – sensitivity) = 1 – 0.75 = 0.25 (or 25%). The false negative rate is not affected by disease prevalence.

(Choice B) The value 37.5% is obtained by dividing the TP (75) by the total number of patients in the study (75 + 25 + 20 + 80 = 200).

(Choice C) The number of patients with myocardial infarction (MI) based on the gold standard is 100 (= 75 + 25). The total number of patients in the study is 200 (= 75 + 25 + 20 + 80). Therefore, the prevalence of MI in this sample is 100/200 = 0.5 (or 50%).



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Sensitivity = TP / (TP + FN), where TP is true positives and FN is false negatives. In this case:

Sensitivity = 75 / (75 + 25) = 75/100 = 0.75 (or 75%)

(Choice A) The false negative rate is (1 – sensitivity) = 1 – 0.75 = 0.25 (or 25%). The false negative rate is not affected by disease prevalence.

(Choice B) The value 37.5% is obtained by dividing the TP (75) by the total number of patients in the study (75 + 25 + 20 + 80 = 200).

(Choice C) The number of patients with myocardial infarction (MI) based on the gold standard is 100 (= 75 + 25). The total number of patients in the study is 200 (= 75 + 25 + 20 + 80). Therefore, the prevalence of MI in this sample is 100/200 = 0.5 (or 50%).

(Choice E) The positive predictive value (PPV) of the test (the probability that a person has the disease given a positive test result) is given by: PPV = TP / (TP + FP), where FP is false positives. In this case, PPV = 75 / (75 + 20) = 75/95 = 0.79 (or 79%).

(Choice F) The test specificity (its ability to correctly identify individuals without the disease) is 80 / (80 + 20) = 80/100 = 0.80 (or 80%).

Educational objective:

Sensitivity = true positives / (true positives + false negatives). Screening tests should have high sensitivity.

Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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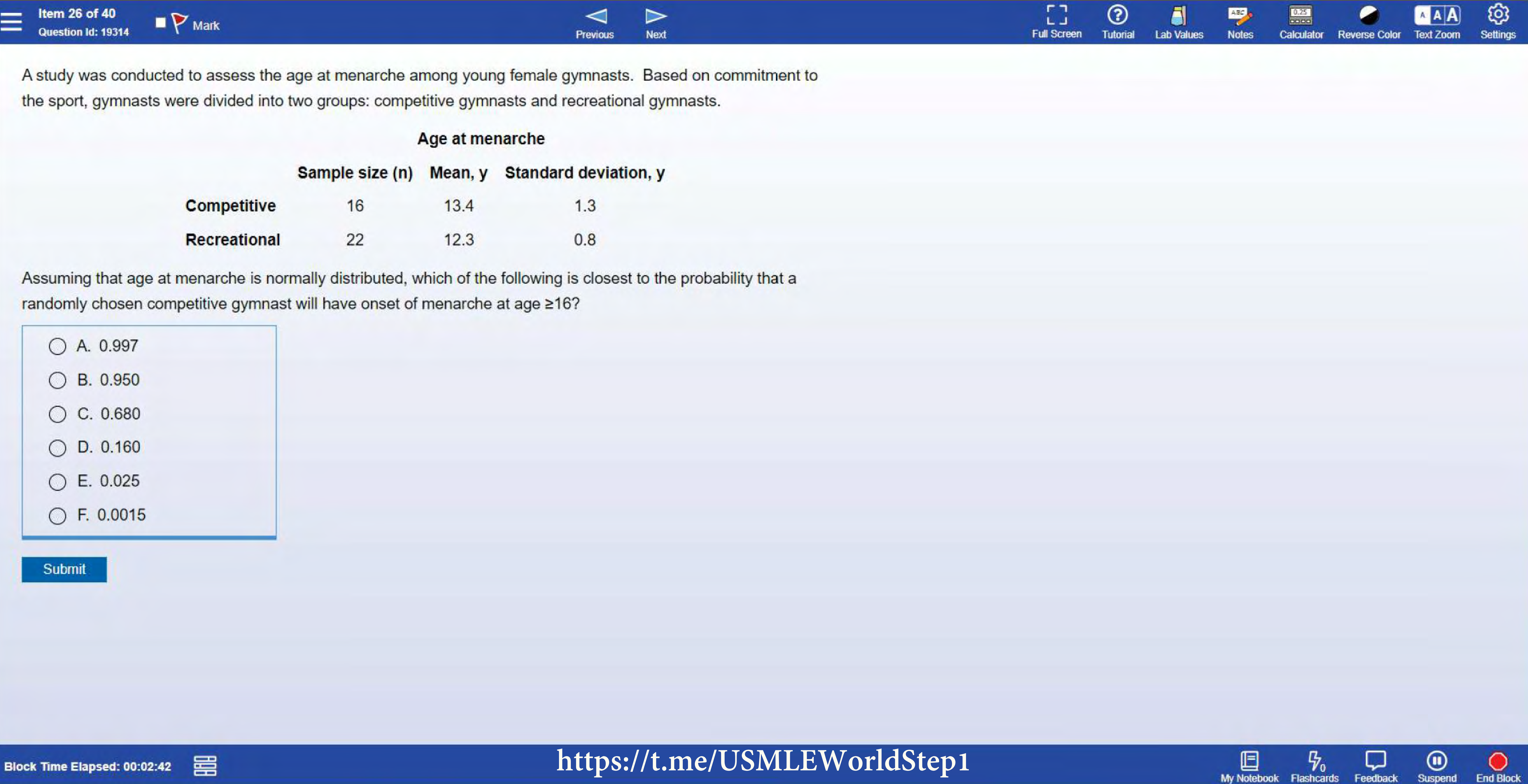
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Question Id: 19314

A study was conducted to assess the age at menarche among young female gymnasts. Based on commitment to the sport, gymnasts were divided into two groups: competitive gymnasts and recreational gymnasts.

	Age at menarche		
	Sample size (n)	**Mean, y**	**Standard deviation, y**
Competitive	16	13.4	1.3
Recreational	22	12.3	0.8

Assuming that age at menarche is normally distributed, which of the following is closest to the probability that a randomly chosen competitive gymnast will have onset of menarche at age ≥16?

- ○ A. 0.997
- ○ B. 0.950
- ○ C. 0.680
- ○ D. 0.160
- ○ E. 0.025
- ○ F. 0.0015

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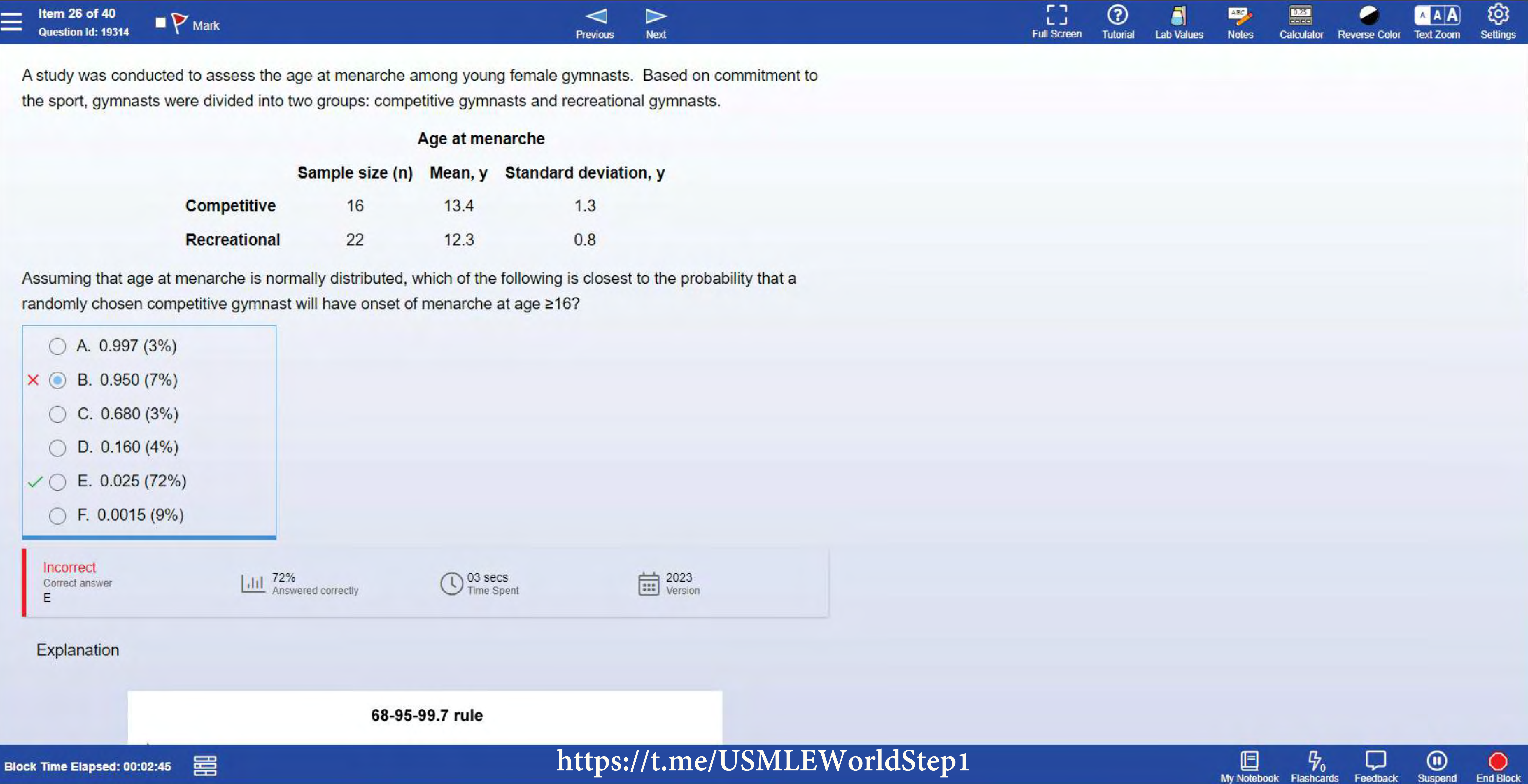
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Age at menarche

	Sample size (n)	Mean, y	Standard deviation, y
Competitive	16	13.4	1.3
Recreational	22	12.3	0.8

Assuming that age at menarche is normally distributed, which of the following is closest to the probability that a randomly chosen competitive gymnast will have onset of menarche at age ≥16?

- ○ A. 0.997 (3%)
- ✗ ● B. 0.950 (7%)
- ○ C. 0.680 (3%)
- ○ D. 0.160 (4%)
- ✓ ○ E. 0.025 (72%)
- ○ F. 0.0015 (9%)

Incorrect
Correct answer
E

72%
Answered correctly

03 secs
Time Spent

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Explanation

68-95-99.7 rule

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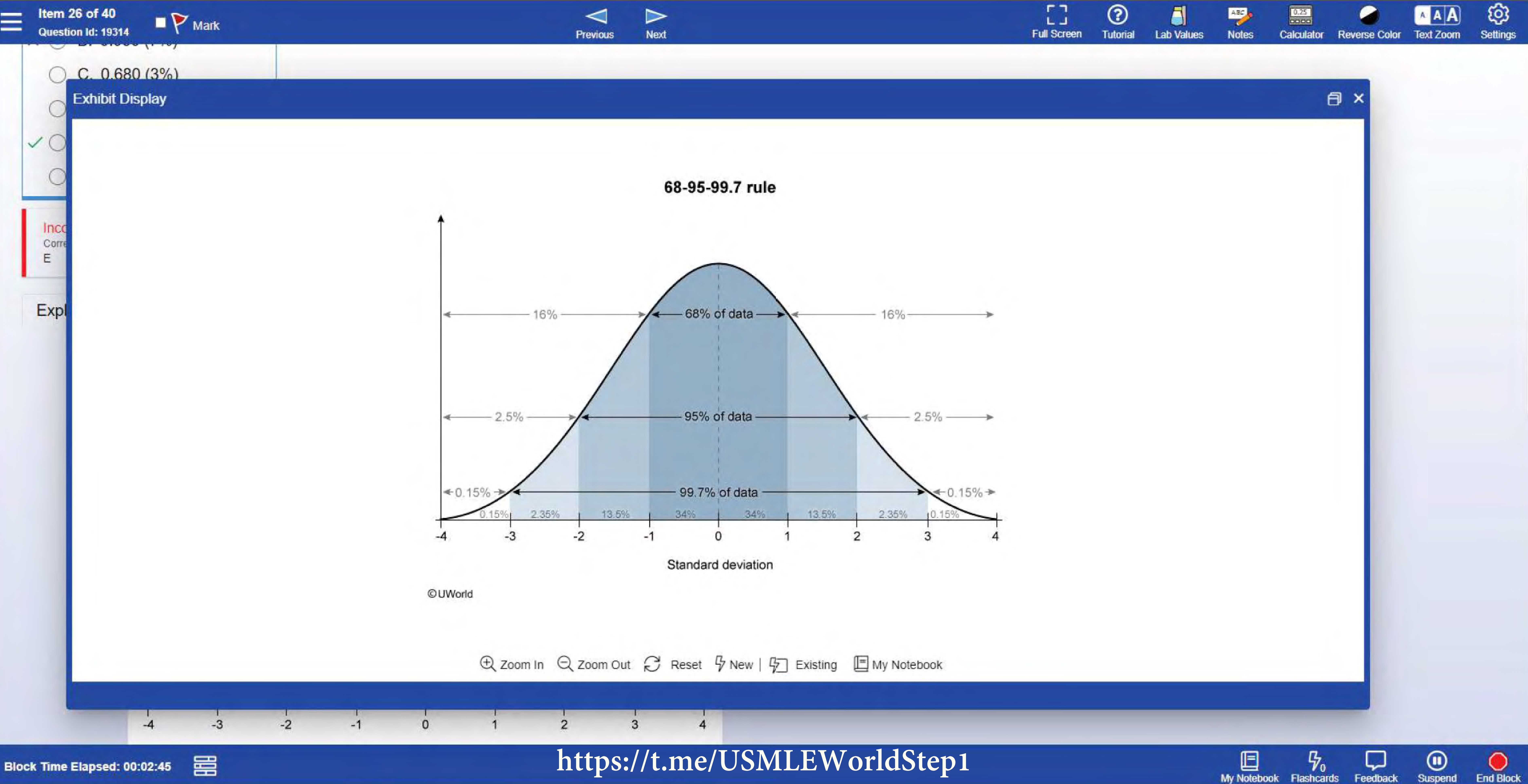

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○ C. 0.680 (3%)

Exhibit Display

68-95-99.7 rule

16%
68% of data
16%
2.5%
95% of data
2.5%
0.15%
99.7% of data
0.15%
0.15%
2.35%
13.5%
34%
34%
13.5%
2.35%
0.15%
-4
-3
-2
-1
0
1
2
3
4
Standard deviation

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New
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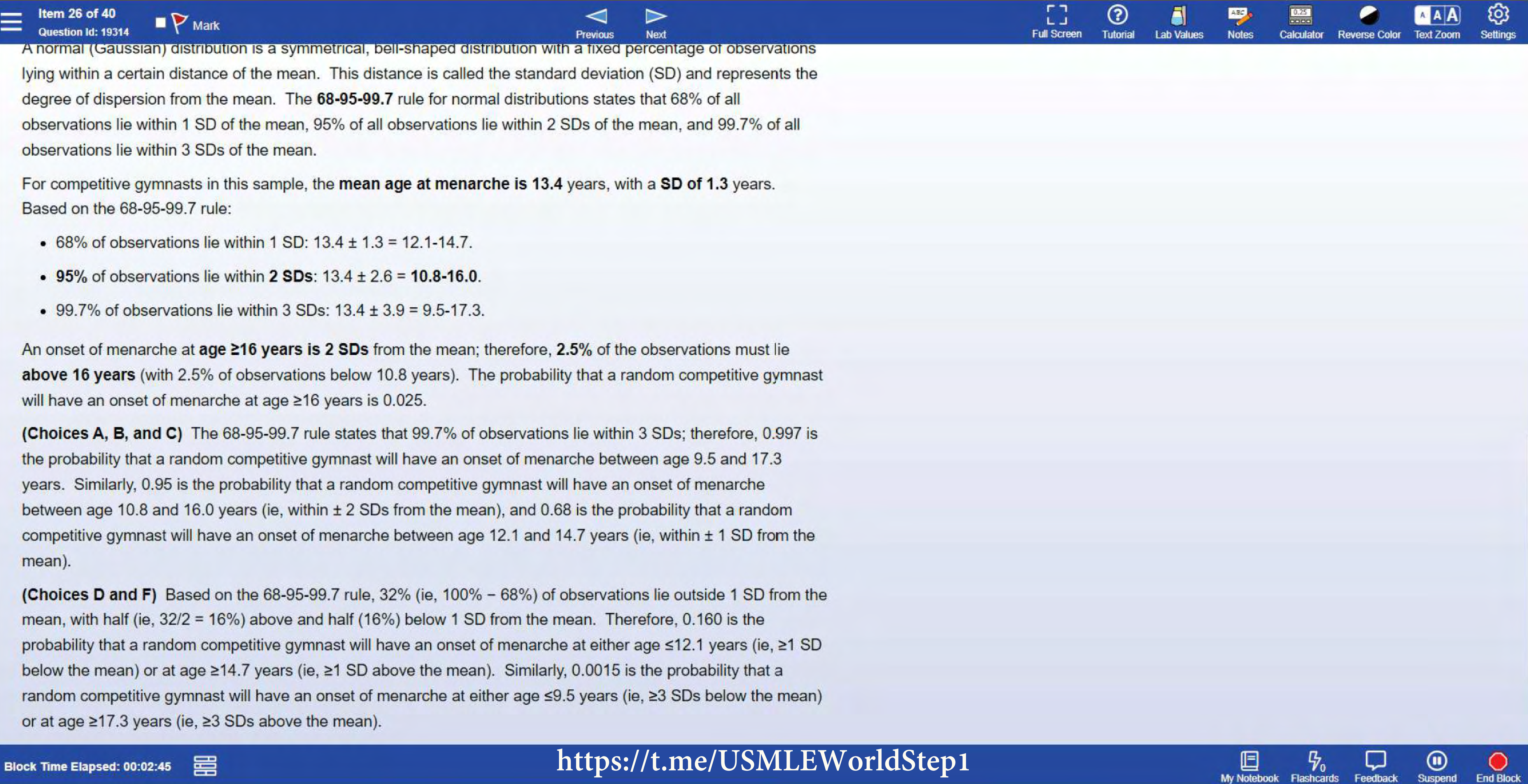


A normal (Gaussian) distribution is a symmetrical, bell-shaped distribution with a fixed percentage of observations lying within a certain distance of the mean. This distance is called the standard deviation (SD) and represents the degree of dispersion from the mean. The **68-95-99.7** rule for normal distributions states that 68% of all observations lie within 1 SD of the mean, 95% of all observations lie within 2 SDs of the mean, and 99.7% of all observations lie within 3 SDs of the mean.

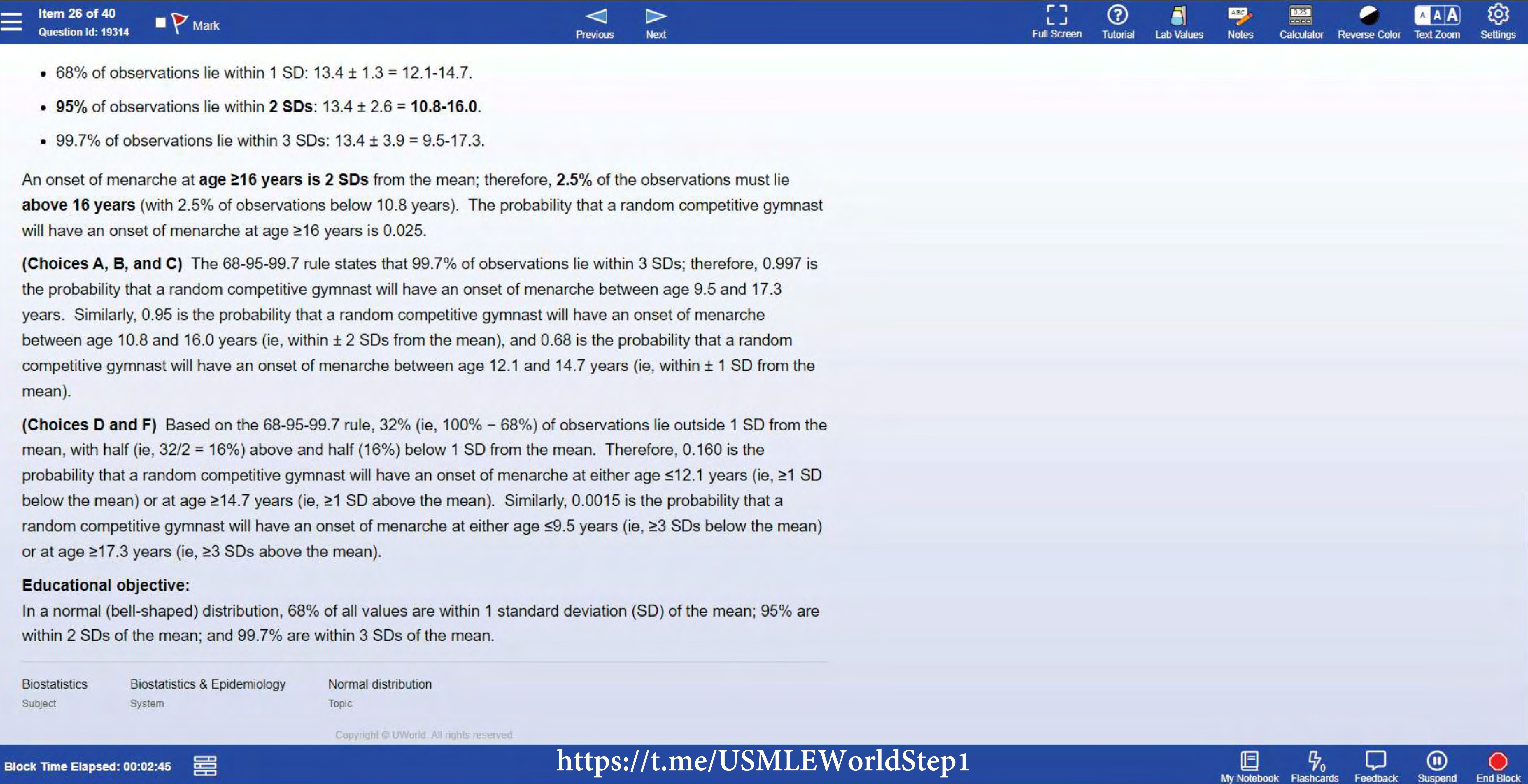
For competitive gymnasts in this sample, the **mean age at menarche is 13.4** years, with a **SD of 1.3** years. Based on the 68-95-99.7 rule:

- 68% of observations lie within 1 SD: 13.4 ± 1.3 = 12.1-14.7.
- **95%** of observations lie within **2 SDs**: 13.4 ± 2.6 = **10.8-16.0**.
- 99.7% of observations lie within 3 SDs: 13.4 ± 3.9 = 9.5-17.3.

An onset of menarche at **age ≥16 years is 2 SDs** from the mean; therefore, **2.5%** of the observations must lie **above 16 years** (with 2.5% of observations below 10.8 years). The probability that a random competitive gymnast will have an onset of menarche at age ≥16 years is 0.025.

(Choices A, B, and C) The 68-95-99.7 rule states that 99.7% of observations lie within 3 SDs; therefore, 0.997 is the probability that a random competitive gymnast will have an onset of menarche between age 9.5 and 17.3 years. Similarly, 0.95 is the probability that a random competitive gymnast will have an onset of menarche between age 10.8 and 16.0 years (ie, within ± 2 SDs from the mean), and 0.68 is the probability that a random competitive gymnast will have an onset of menarche between age 12.1 and 14.7 years (ie, within ± 1 SD from the mean).

(Choices D and F) Based on the 68-95-99.7 rule, 32% (ie, 100% − 68%) of observations lie outside 1 SD from the mean, with half (ie, 32/2 = 16%) above and half (16%) below 1 SD from the mean. Therefore, 0.160 is the probability that a random competitive gymnast will have an onset of menarche at either age ≤12.1 years (ie, ≥1 SD below the mean) or at age ≥14.7 years (ie, ≥1 SD above the mean). Similarly, 0.0015 is the probability that a random competitive gymnast will have an onset of menarche at either age ≤9.5 years (ie, ≥3 SDs below the mean) or at age ≥17.3 years (ie, ≥3 SDs above the mean).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- 99.7% of observations lie within 3 SDs: 13.4 ± 3.9 = 9.5-17.3.

An onset of menarche at **age ≥16 years is 2 SDs** from the mean; therefore, **2.5%** of the observations must lie **above 16 years** (with 2.5% of observations below 10.8 years). The probability that a random competitive gymnast will have an onset of menarche at age ≥16 years is 0.025.

(Choices A, B, and C) The 68-95-99.7 rule states that 99.7% of observations lie within 3 SDs; therefore, 0.997 is the probability that a random competitive gymnast will have an onset of menarche between age 9.5 and 17.3 years. Similarly, 0.95 is the probability that a random competitive gymnast will have an onset of menarche between age 10.8 and 16.0 years (ie, within ± 2 SDs from the mean), and 0.68 is the probability that a random competitive gymnast will have an onset of menarche between age 12.1 and 14.7 years (ie, within ± 1 SD from the mean).

(Choices D and F) Based on the 68-95-99.7 rule, 32% (ie, 100% − 68%) of observations lie outside 1 SD from the mean, with half (ie, 32/2 = 16%) above and half (16%) below 1 SD from the mean. Therefore, 0.160 is the probability that a random competitive gymnast will have an onset of menarche at either age ≤12.1 years (ie, ≥1 SD below the mean) or at age ≥14.7 years (ie, ≥1 SD above the mean). Similarly, 0.0015 is the probability that a random competitive gymnast will have an onset of menarche at either age ≤9.5 years (ie, ≥3 SDs below the mean) or at age ≥17.3 years (ie, ≥3 SDs above the mean).

Educational objective:

In a normal (bell-shaped) distribution, 68% of all values are within 1 standard deviation (SD) of the mean; 95% are within 2 SDs of the mean; and 99.7% are within 3 SDs of the mean.

Biostatistics	Biostatistics & Epidemiology	Normal distribution
Subject	System	Topic

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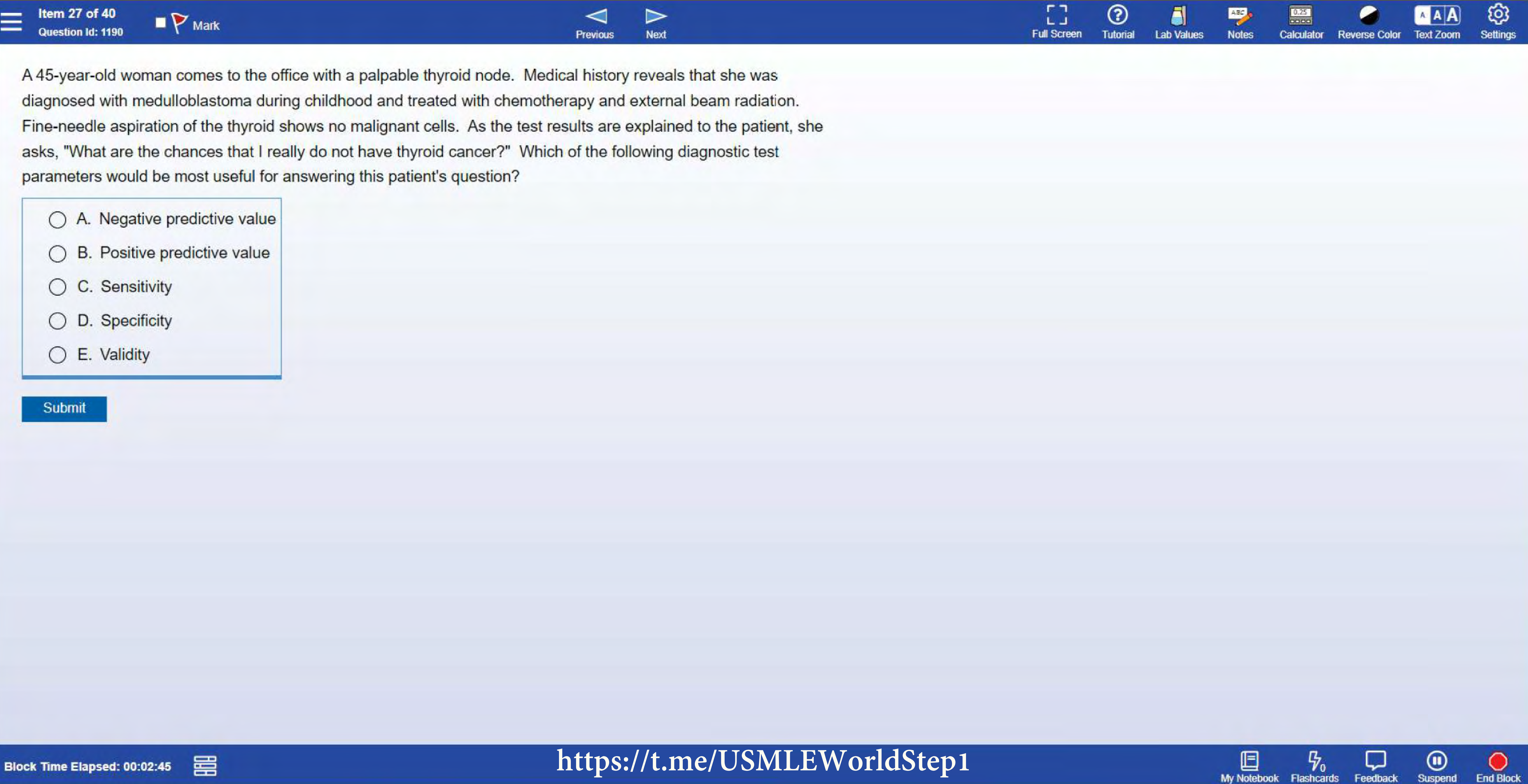
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A 45-year-old woman comes to the office with a palpable thyroid node. Medical history reveals that she was diagnosed with medulloblastoma during childhood and treated with chemotherapy and external beam radiation. Fine-needle aspiration of the thyroid shows no malignant cells. As the test results are explained to the patient, she asks, "What are the chances that I really do not have thyroid cancer?" Which of the following diagnostic test parameters would be most useful for answering this patient's question?

○ A. Negative predictive value
○ B. Positive predictive value
○ C. Sensitivity
○ D. Specificity
○ E. Validity

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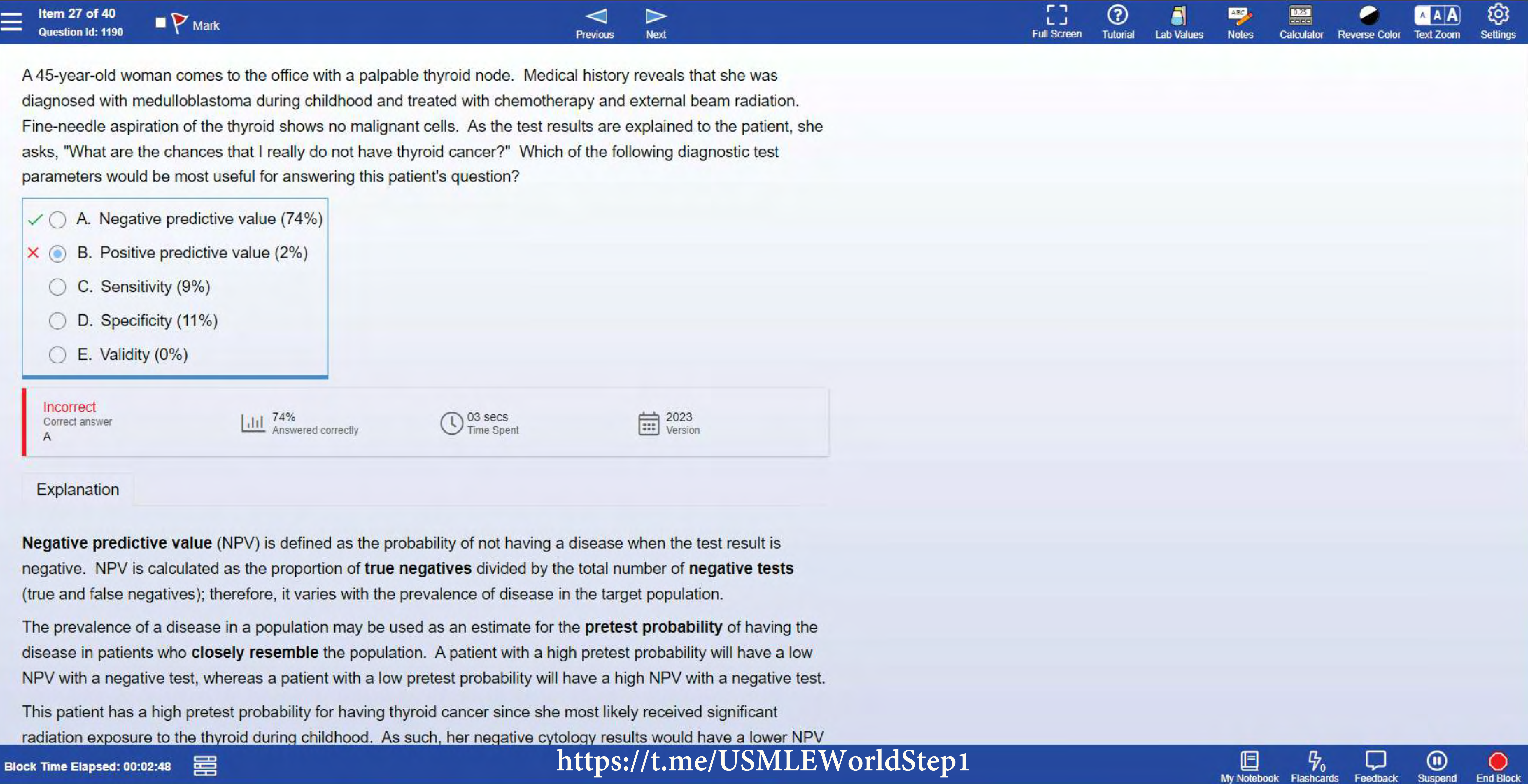
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A 45-year-old woman comes to the office with a palpable thyroid node. Medical history reveals that she was diagnosed with medulloblastoma during childhood and treated with chemotherapy and external beam radiation. Fine-needle aspiration of the thyroid shows no malignant cells. As the test results are explained to the patient, she asks, "What are the chances that I really do not have thyroid cancer?" Which of the following diagnostic test parameters would be most useful for answering this patient's question?

✓ ○ A. Negative predictive value (74%)
✗ ● B. Positive predictive value (2%)
○ C. Sensitivity (9%)
○ D. Specificity (11%)
○ E. Validity (0%)

Incorrect
Correct answer
A

74%
Answered correctly

03 secs
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Explanation

Negative predictive value (NPV) is defined as the probability of not having a disease when the test result is negative. NPV is calculated as the proportion of **true negatives** divided by the total number of **negative tests** (true and false negatives); therefore, it varies with the prevalence of disease in the target population.

The prevalence of a disease in a population may be used as an estimate for the **pretest probability** of having the disease in patients who **closely resemble** the population. A patient with a high pretest probability will have a low NPV with a negative test, whereas a patient with a low pretest probability will have a high NPV with a negative test.

This patient has a high pretest probability for having thyroid cancer since she most likely received significant radiation exposure to the thyroid during childhood. As such, her negative cytology results would have a lower NPV

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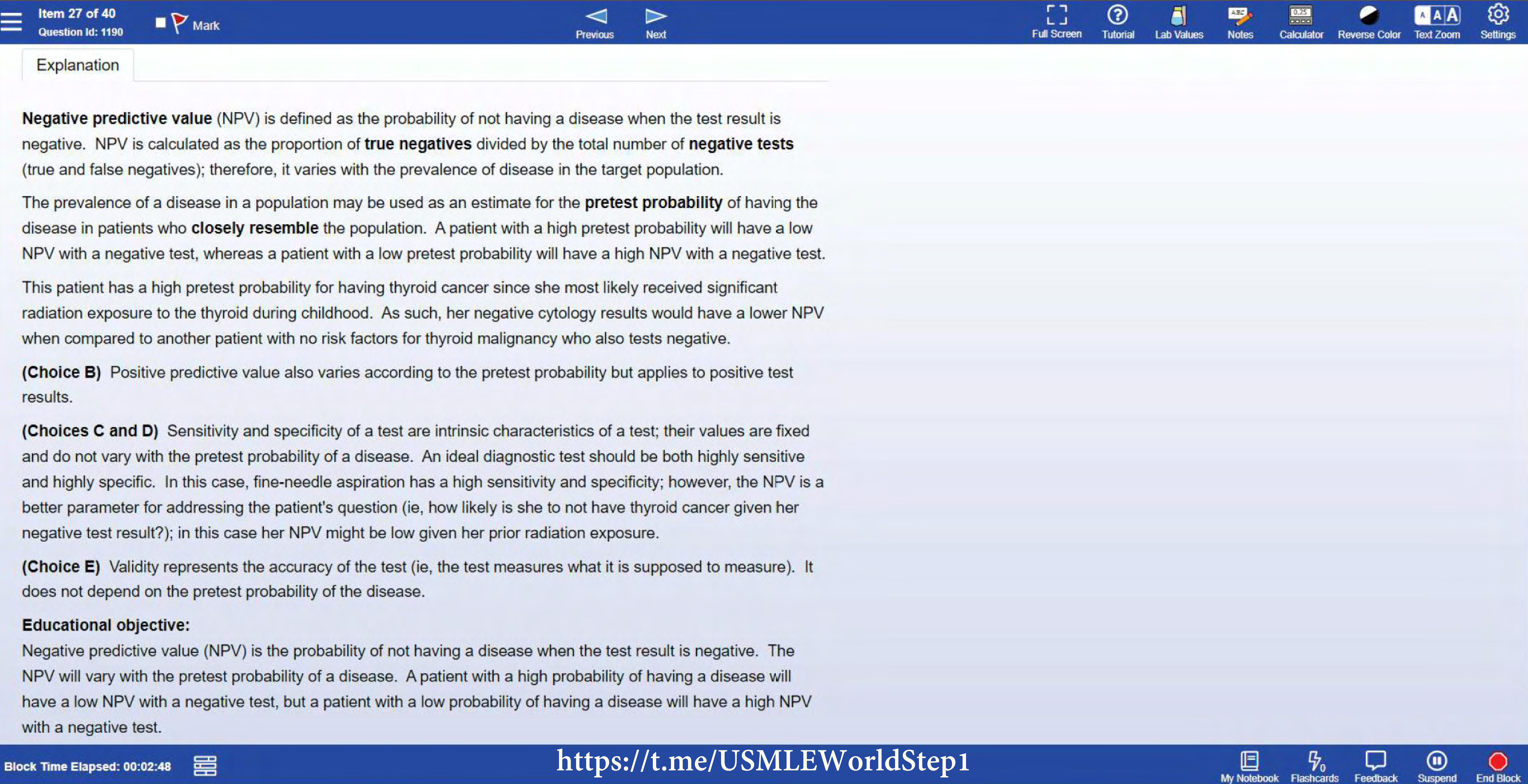


Negative predictive value (NPV) is defined as the probability of not having a disease when the test result is negative. NPV is calculated as the proportion of **true negatives** divided by the total number of **negative tests** (true and false negatives); therefore, it varies with the prevalence of disease in the target population.

The prevalence of a disease in a population may be used as an estimate for the **pretest probability** of having the disease in patients who **closely resemble** the population. A patient with a high pretest probability will have a low NPV with a negative test, whereas a patient with a low pretest probability will have a high NPV with a negative test.

This patient has a high pretest probability for having thyroid cancer since she most likely received significant radiation exposure to the thyroid during childhood. As such, her negative cytology results would have a lower NPV when compared to another patient with no risk factors for thyroid malignancy who also tests negative.

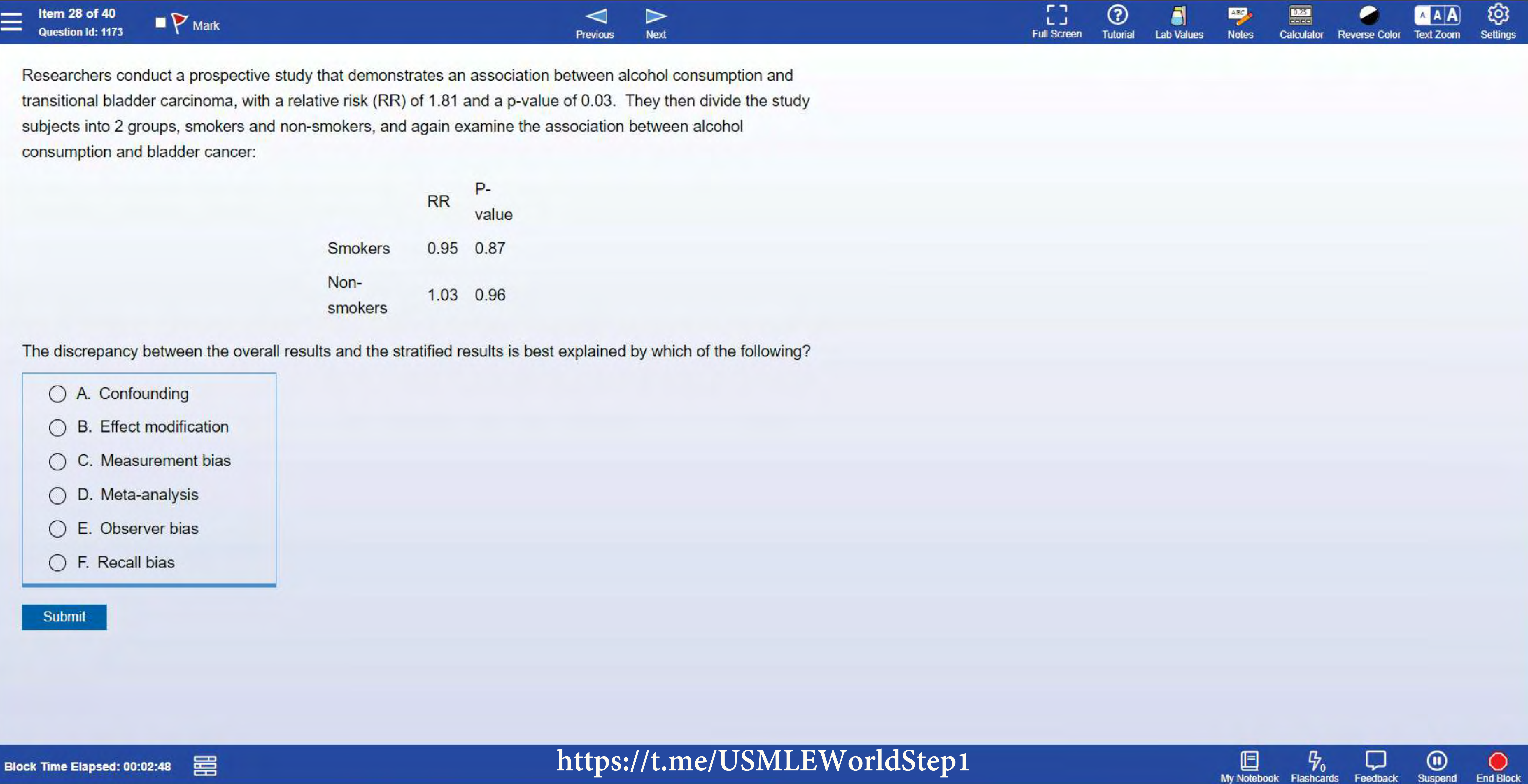
(Choice B) Positive predictive value also varies according to the pretest probability but applies to positive test results.

(Choices C and D) Sensitivity and specificity of a test are intrinsic characteristics of a test; their values are fixed and do not vary with the pretest probability of a disease. An ideal diagnostic test should be both highly sensitive and highly specific. In this case, fine-needle aspiration has a high sensitivity and specificity; however, the NPV is a better parameter for addressing the patient's question (ie, how likely is she to not have thyroid cancer given her negative test result?); in this case her NPV might be low given her prior radiation exposure.

(Choice E) Validity represents the accuracy of the test (ie, the test measures what it is supposed to measure). It does not depend on the pretest probability of the disease.

Educational objective:

Negative predictive value (NPV) is the probability of not having a disease when the test result is negative. The NPV will vary with the pretest probability of a disease. A patient with a high probability of having a disease will have a low NPV with a negative test, but a patient with a low probability of having a disease will have a high NPV with a negative test.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Researchers conduct a prospective study that demonstrates an association between alcohol consumption and transitional bladder carcinoma, with a relative risk (RR) of 1.81 and a p-value of 0.03. They then divide the study subjects into 2 groups, smokers and non-smokers, and again examine the association between alcohol consumption and bladder cancer:

	RR	P-value
Smokers	0.95	0.87
Non-smokers	1.03	0.96

The discrepancy between the overall results and the stratified results is best explained by which of the following?

- ○ A. Confounding
- ○ B. Effect modification
- ○ C. Measurement bias
- ○ D. Meta-analysis
- ○ E. Observer bias
- ○ F. Recall bias

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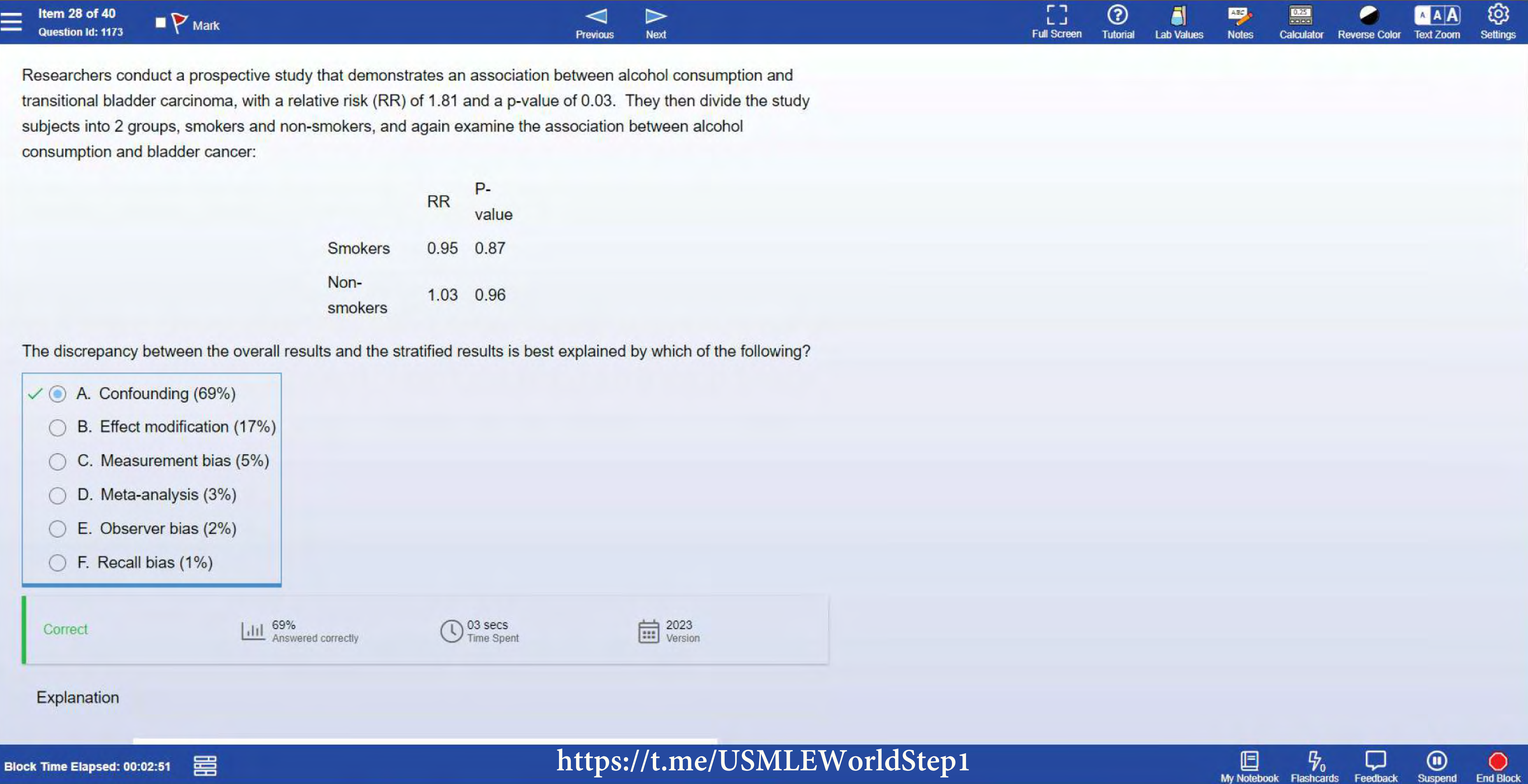
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	RR	P-value
Smokers	0.95	0.87
Non-smokers	1.03	0.96

The discrepancy between the overall results and the stratified results is best explained by which of the following?

✓ ● A. Confounding (69%)
○ B. Effect modification (17%)
○ C. Measurement bias (5%)
○ D. Meta-analysis (3%)
○ E. Observer bias (2%)
○ F. Recall bias (1%)

Correct

69% Answered correctly

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Explanation

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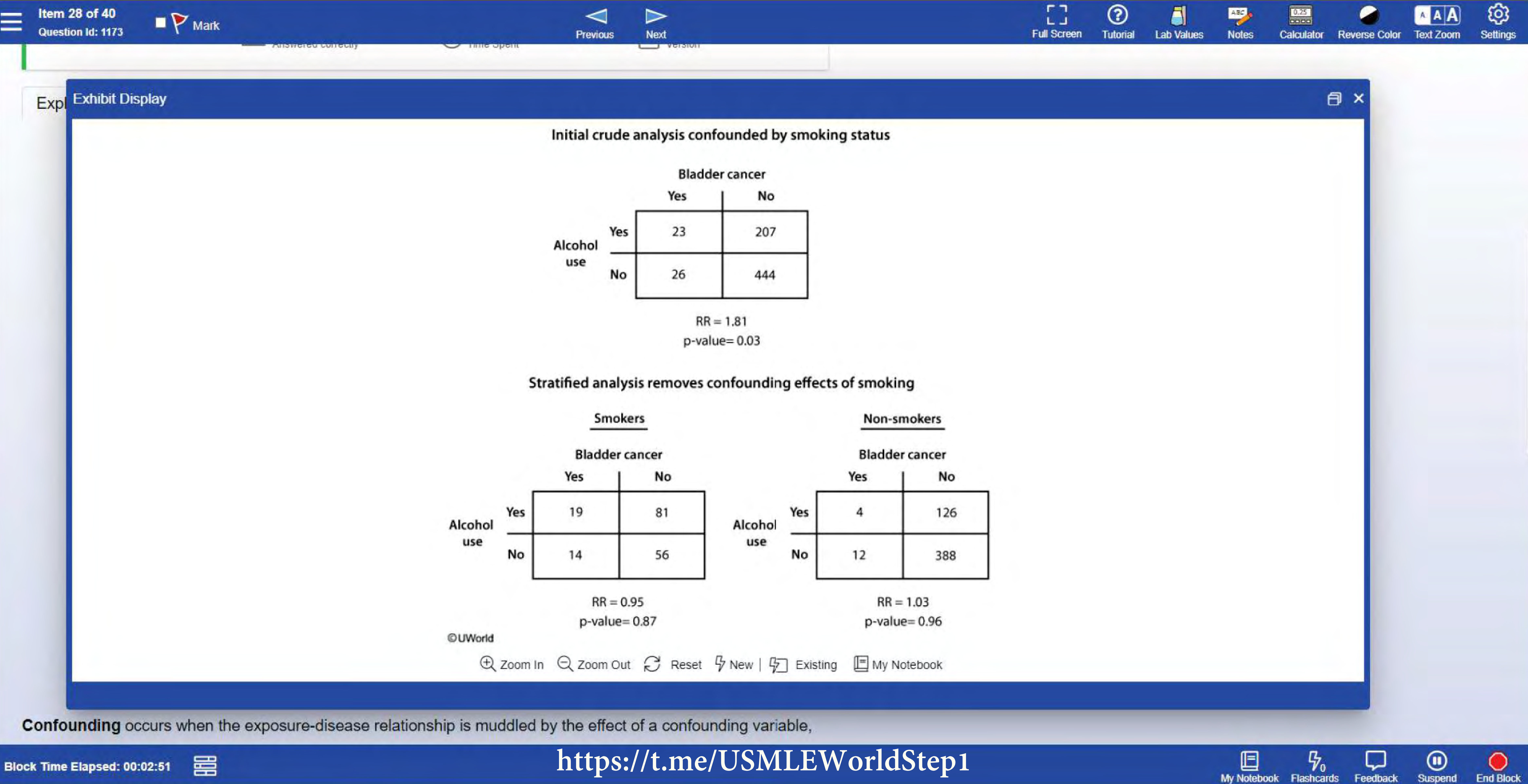
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Initial crude analysis confounded by smoking status

Alcohol use	Bladder cancer: Yes	Bladder cancer: No
Yes	23	207
No	26	444

RR = 1.81
p-value= 0.03

Stratified analysis removes confounding effects of smoking

Smokers

Alcohol use	Bladder cancer: Yes	Bladder cancer: No
Yes	19	81
No	14	56

RR = 0.95
p-value= 0.87

Non-smokers

Alcohol use	Bladder cancer: Yes	Bladder cancer: No
Yes	4	126
No	12	388

RR = 1.03
p-value= 0.96

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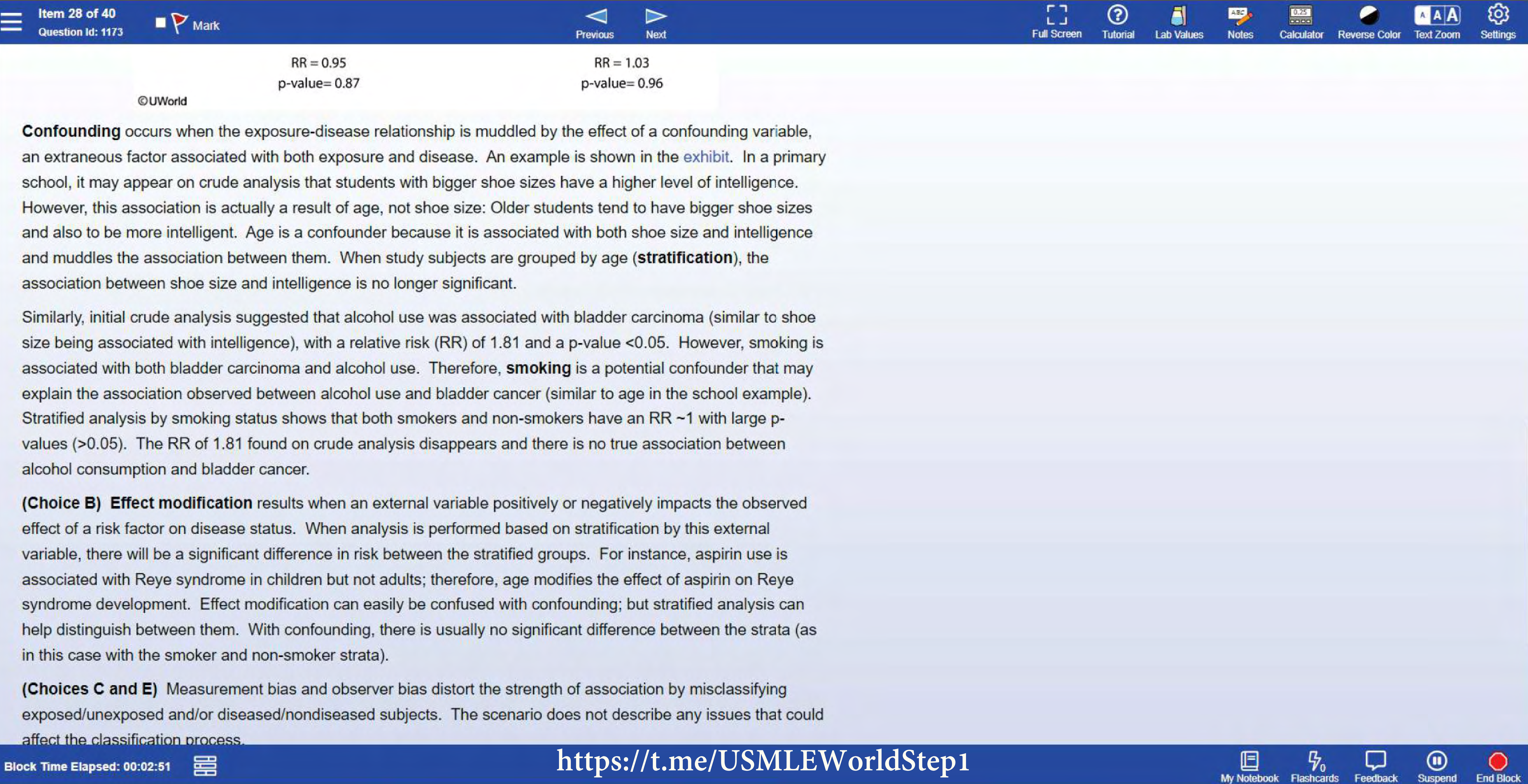
Confounding occurs when the exposure-disease relationship is muddled by the effect of a confounding variable,



RR = 0.95
p-value= 0.87

RR = 1.03
p-value= 0.96

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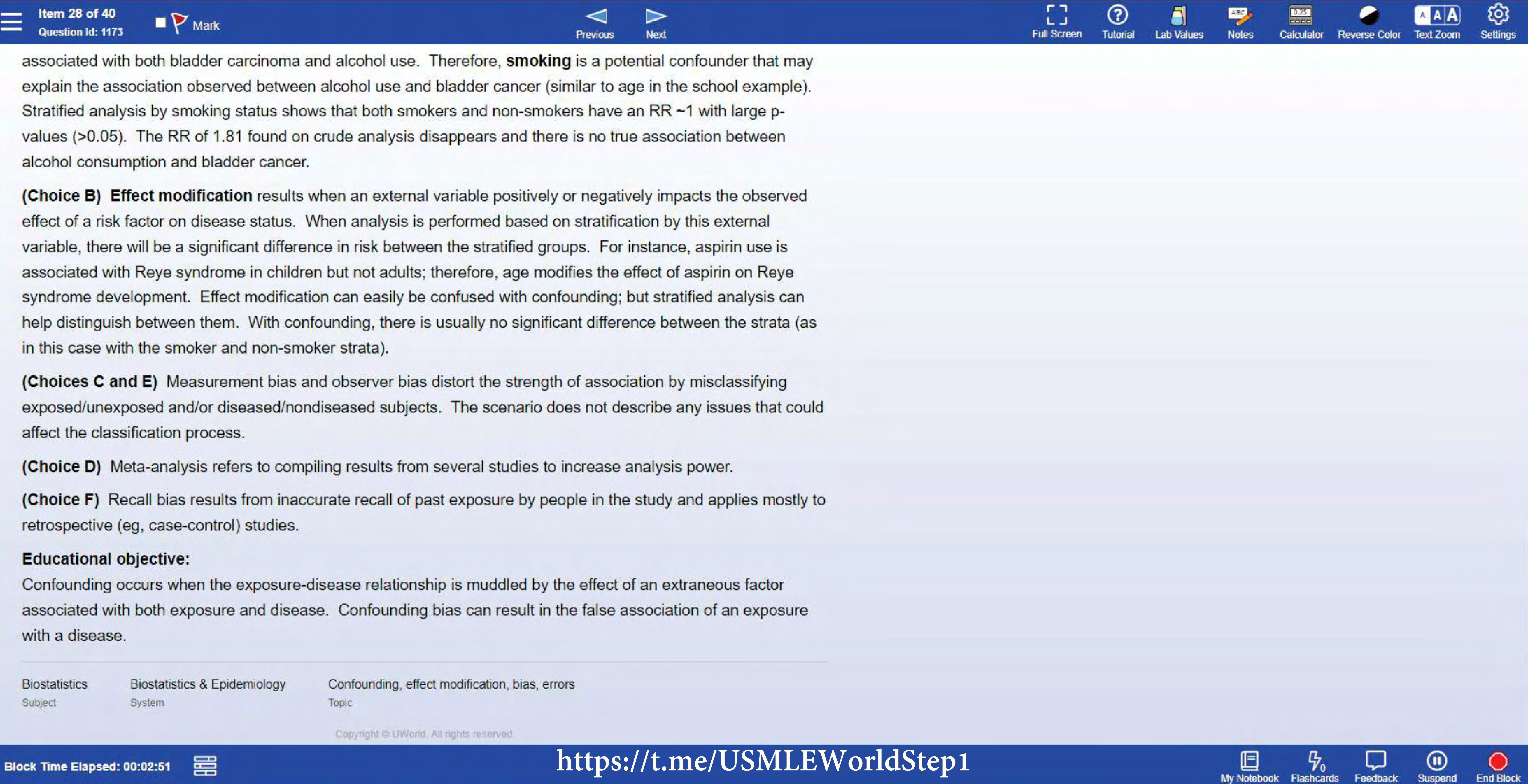
Confounding occurs when the exposure-disease relationship is muddled by the effect of a confounding variable, an extraneous factor associated with both exposure and disease. An example is shown in the exhibit. In a primary school, it may appear on crude analysis that students with bigger shoe sizes have a higher level of intelligence. However, this association is actually a result of age, not shoe size: Older students tend to have bigger shoe sizes and also to be more intelligent. Age is a confounder because it is associated with both shoe size and intelligence and muddles the association between them. When study subjects are grouped by age (**stratification**), the association between shoe size and intelligence is no longer significant.

Similarly, initial crude analysis suggested that alcohol use was associated with bladder carcinoma (similar to shoe size being associated with intelligence), with a relative risk (RR) of 1.81 and a p-value <0.05. However, smoking is associated with both bladder carcinoma and alcohol use. Therefore, **smoking** is a potential confounder that may explain the association observed between alcohol use and bladder cancer (similar to age in the school example). Stratified analysis by smoking status shows that both smokers and non-smokers have an RR ~1 with large p-values (>0.05). The RR of 1.81 found on crude analysis disappears and there is no true association between alcohol consumption and bladder cancer.

(Choice B) Effect modification results when an external variable positively or negatively impacts the observed effect of a risk factor on disease status. When analysis is performed based on stratification by this external variable, there will be a significant difference in risk between the stratified groups. For instance, aspirin use is associated with Reye syndrome in children but not adults; therefore, age modifies the effect of aspirin on Reye syndrome development. Effect modification can easily be confused with confounding; but stratified analysis can help distinguish between them. With confounding, there is usually no significant difference between the strata (as in this case with the smoker and non-smoker strata).

(Choices C and E) Measurement bias and observer bias distort the strength of association by misclassifying exposed/unexposed and/or diseased/nondiseased subjects. The scenario does not describe any issues that could affect the classification process.



associated with both bladder carcinoma and alcohol use. Therefore, **smoking** is a potential confounder that may explain the association observed between alcohol use and bladder cancer (similar to age in the school example). Stratified analysis by smoking status shows that both smokers and non-smokers have an RR ~1 with large p-values (>0.05). The RR of 1.81 found on crude analysis disappears and there is no true association between alcohol consumption and bladder cancer.

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(Choices C and E) Measurement bias and observer bias distort the strength of association by misclassifying exposed/unexposed and/or diseased/nondiseased subjects. The scenario does not describe any issues that could affect the classification process.

(Choice D) Meta-analysis refers to compiling results from several studies to increase analysis power.

(Choice F) Recall bias results from inaccurate recall of past exposure by people in the study and applies mostly to retrospective (eg, case-control) studies.

Educational objective:

Confounding occurs when the exposure-disease relationship is muddled by the effect of an extraneous factor associated with both exposure and disease. Confounding bias can result in the false association of an exposure with a disease.

Biostatistics	Biostatistics & Epidemiology	Confounding, effect modification, bias, errors
Subject	System	Topic

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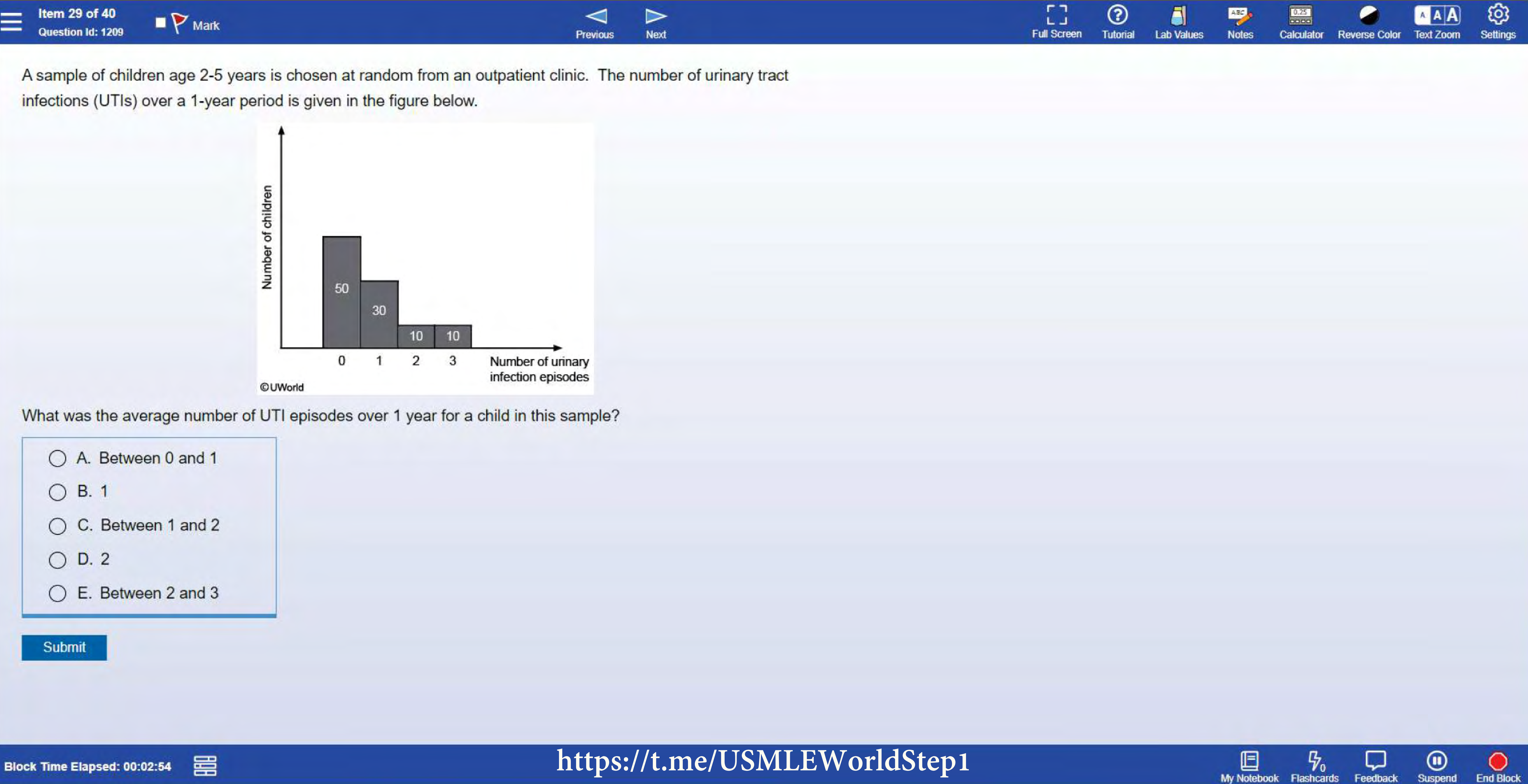
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Number of children
50
30
10
10
0
1
2
3
Number of urinary infection episodes
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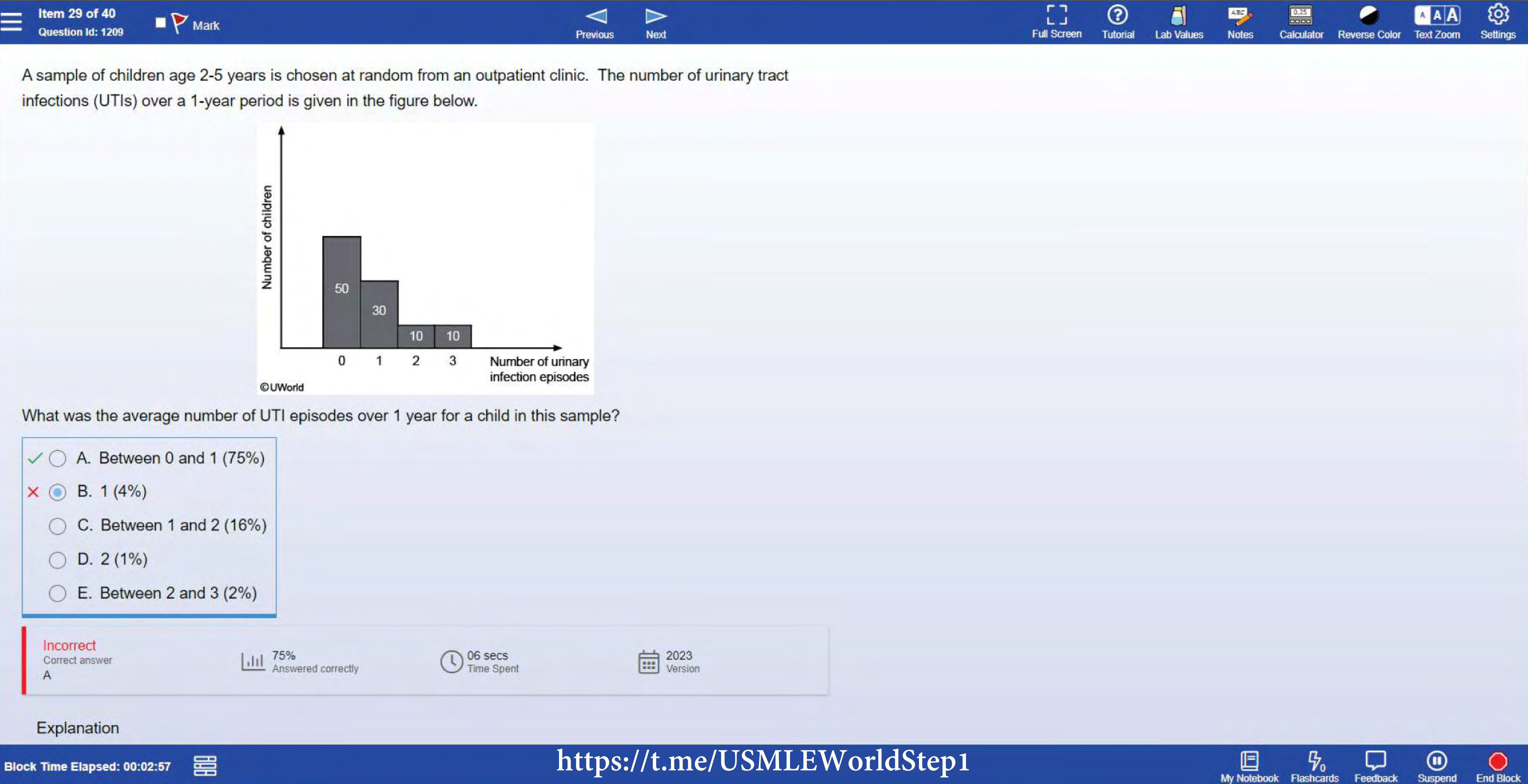
A sample of children age 2-5 years is chosen at random from an outpatient clinic. The number of urinary tract infections (UTIs) over a 1-year period is given in the figure below.

What was the average number of UTI episodes over 1 year for a child in this sample?

○ A. Between 0 and 1
○ B. 1
○ C. Between 1 and 2
○ D. 2
○ E. Between 2 and 3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A sample of children age 2-5 years is chosen at random from an outpatient clinic. The number of urinary tract infections (UTIs) over a 1-year period is given in the figure below.

Number of children
50
30
10
10
0
1
2
3
Number of urinary infection episodes
©UWorld

What was the average number of UTI episodes over 1 year for a child in this sample?

✓ ○ A. Between 0 and 1 (75%)

✗ ● B. 1 (4%)

○ C. Between 1 and 2 (16%)

○ D. 2 (1%)

○ E. Between 2 and 3 (2%)

Incorrect
Correct answer
A

75%
Answered correctly

06 secs
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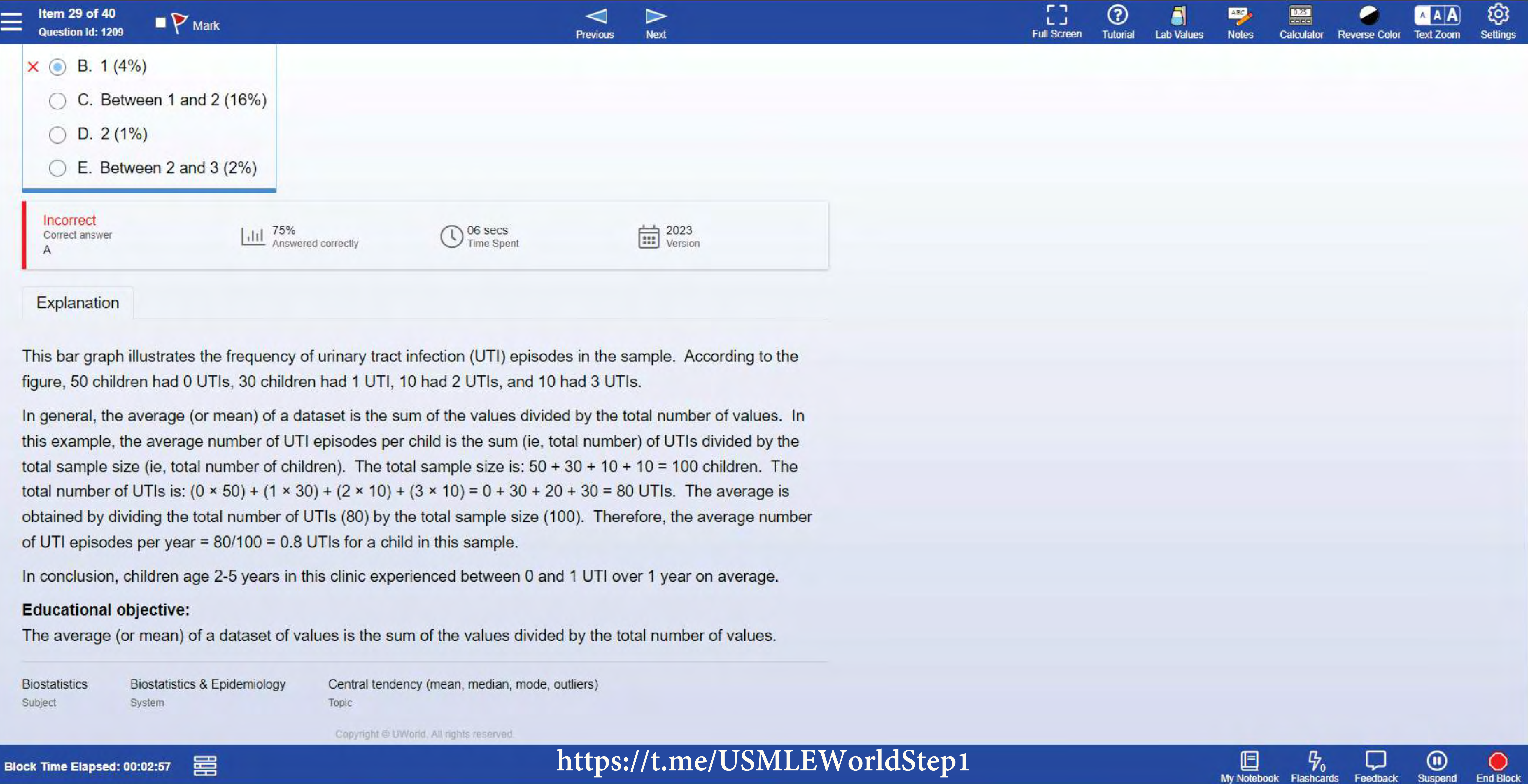
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✕ ● B. 1 (4%)

○ C. Between 1 and 2 (16%)

○ D. 2 (1%)

○ E. Between 2 and 3 (2%)

Incorrect
Correct answer
A

75%
Answered correctly

06 secs
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Explanation

This bar graph illustrates the frequency of urinary tract infection (UTI) episodes in the sample. According to the figure, 50 children had 0 UTIs, 30 children had 1 UTI, 10 had 2 UTIs, and 10 had 3 UTIs.

In general, the average (or mean) of a dataset is the sum of the values divided by the total number of values. In this example, the average number of UTI episodes per child is the sum (ie, total number) of UTIs divided by the total sample size (ie, total number of children). The total sample size is: 50 + 30 + 10 + 10 = 100 children. The total number of UTIs is: (0 × 50) + (1 × 30) + (2 × 10) + (3 × 10) = 0 + 30 + 20 + 30 = 80 UTIs. The average is obtained by dividing the total number of UTIs (80) by the total sample size (100). Therefore, the average number of UTI episodes per year = 80/100 = 0.8 UTIs for a child in this sample.

In conclusion, children age 2-5 years in this clinic experienced between 0 and 1 UTI over 1 year on average.

Educational objective:
The average (or mean) of a dataset of values is the sum of the values divided by the total number of values.

Biostatistics	Biostatistics & Epidemiology	Central tendency (mean, median, mode, outliers)
Subject	System	Topic

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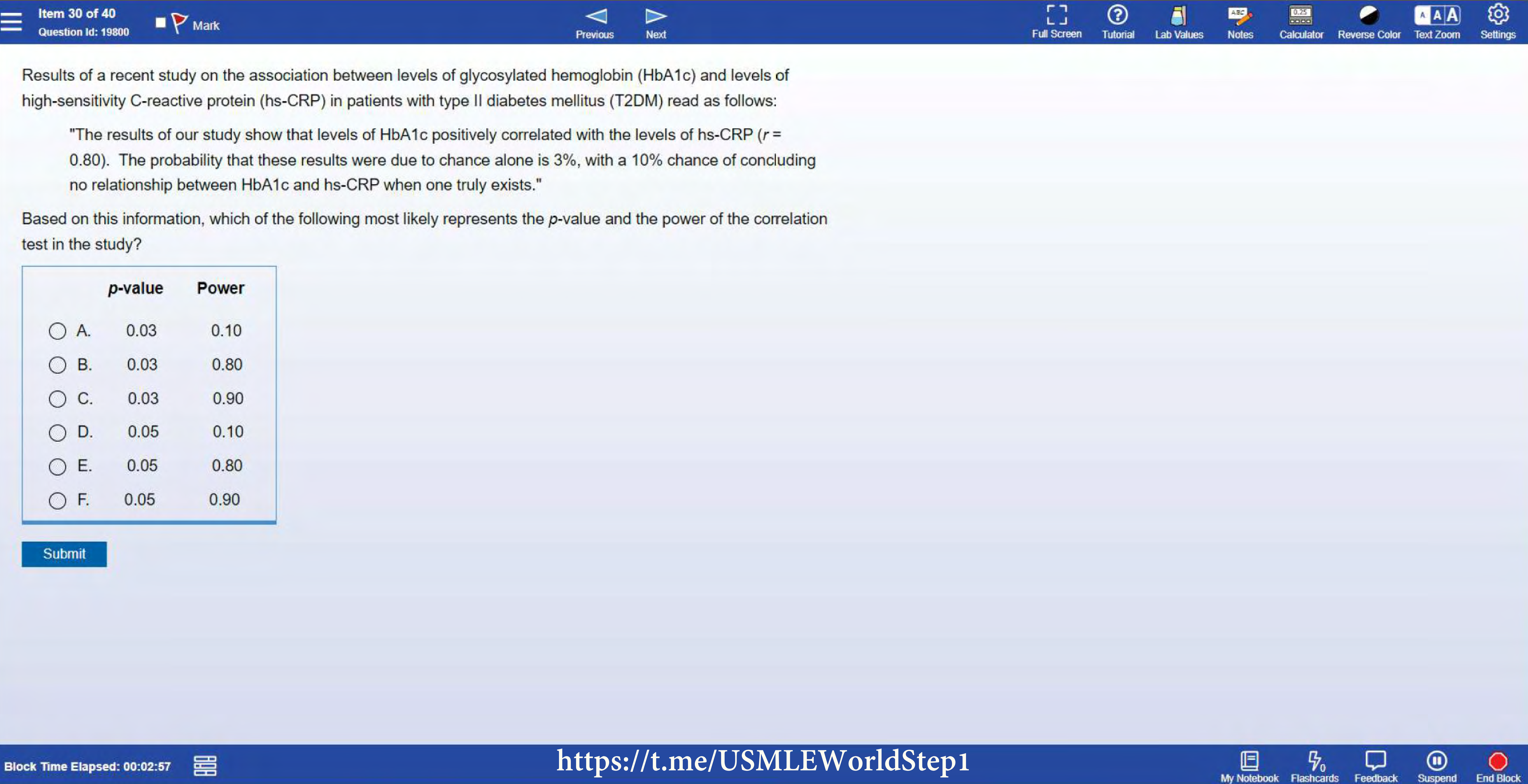
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Results of a recent study on the association between levels of glycosylated hemoglobin (HbA1c) and levels of high-sensitivity C-reactive protein (hs-CRP) in patients with type II diabetes mellitus (T2DM) read as follows:

> "The results of our study show that levels of HbA1c positively correlated with the levels of hs-CRP (r = 0.80). The probability that these results were due to chance alone is 3%, with a 10% chance of concluding no relationship between HbA1c and hs-CRP when one truly exists."

Based on this information, which of the following most likely represents the *p*-value and the power of the correlation test in the study?

	p-value	Power
○ A.	0.03	0.10
○ B.	0.03	0.80
○ C.	0.03	0.90
○ D.	0.05	0.10
○ E.	0.05	0.80
○ F.	0.05	0.90

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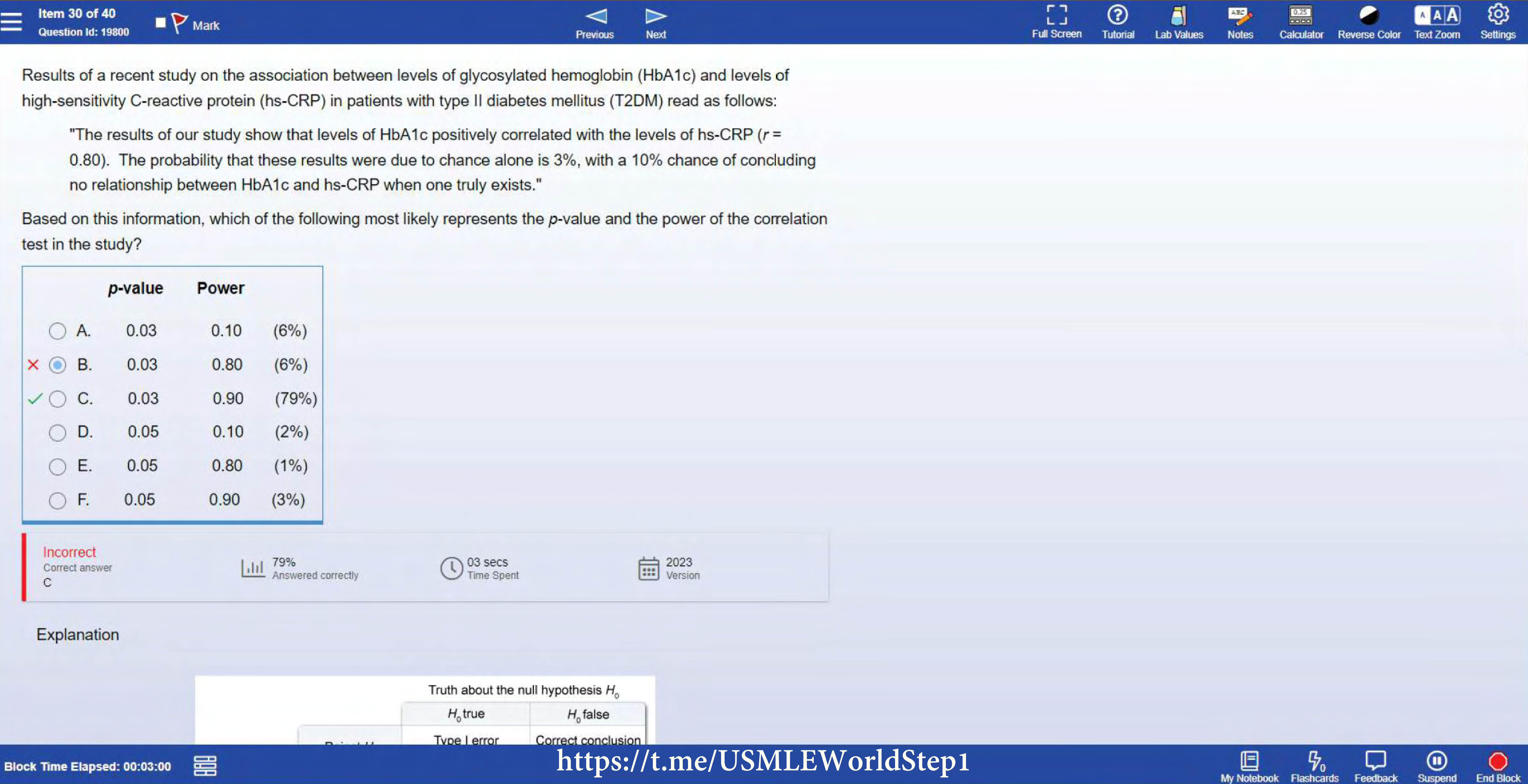
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Based on this information, which of the following most likely represents the *p*-value and the power of the correlation test in the study?

		p-value	Power	
	○ A.	0.03	0.10	(6%)
✗	● B.	0.03	0.80	(6%)
✓	○ C.	0.03	0.90	(79%)
	○ D.	0.05	0.10	(2%)
	○ E.	0.05	0.80	(1%)
	○ F.	0.05	0.90	(3%)

Incorrect
Correct answer
C

79%
Answered correctly

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Explanation

Truth about the null hypothesis H_0

	H_0 true	H_0 false
Reject H	Type I error	Correct conclusion

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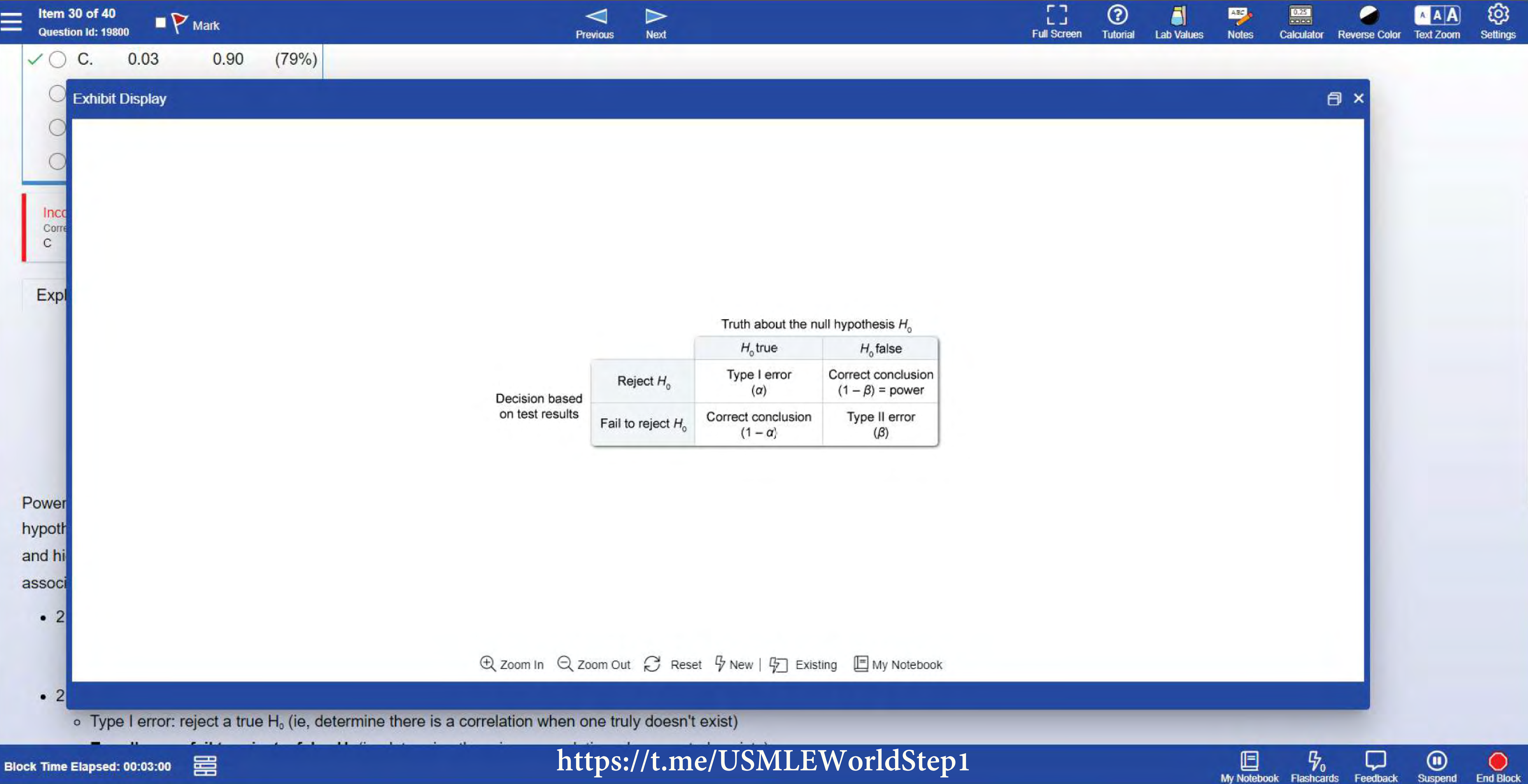
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✓ ○ C. 0.03 0.90 (79%)

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Expl

Truth about the null hypothesis H_0

Decision based on test results		H_0 true	H_0 false
	Reject H_0	Type I error (α)	Correct conclusion ($1 - \beta$) = power
	Fail to reject H_0	Correct conclusion ($1 - \alpha$)	Type II error (β)

Power

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  - Type I error: reject a true H_0 (ie, determine there is a correlation when one truly doesn't exist)

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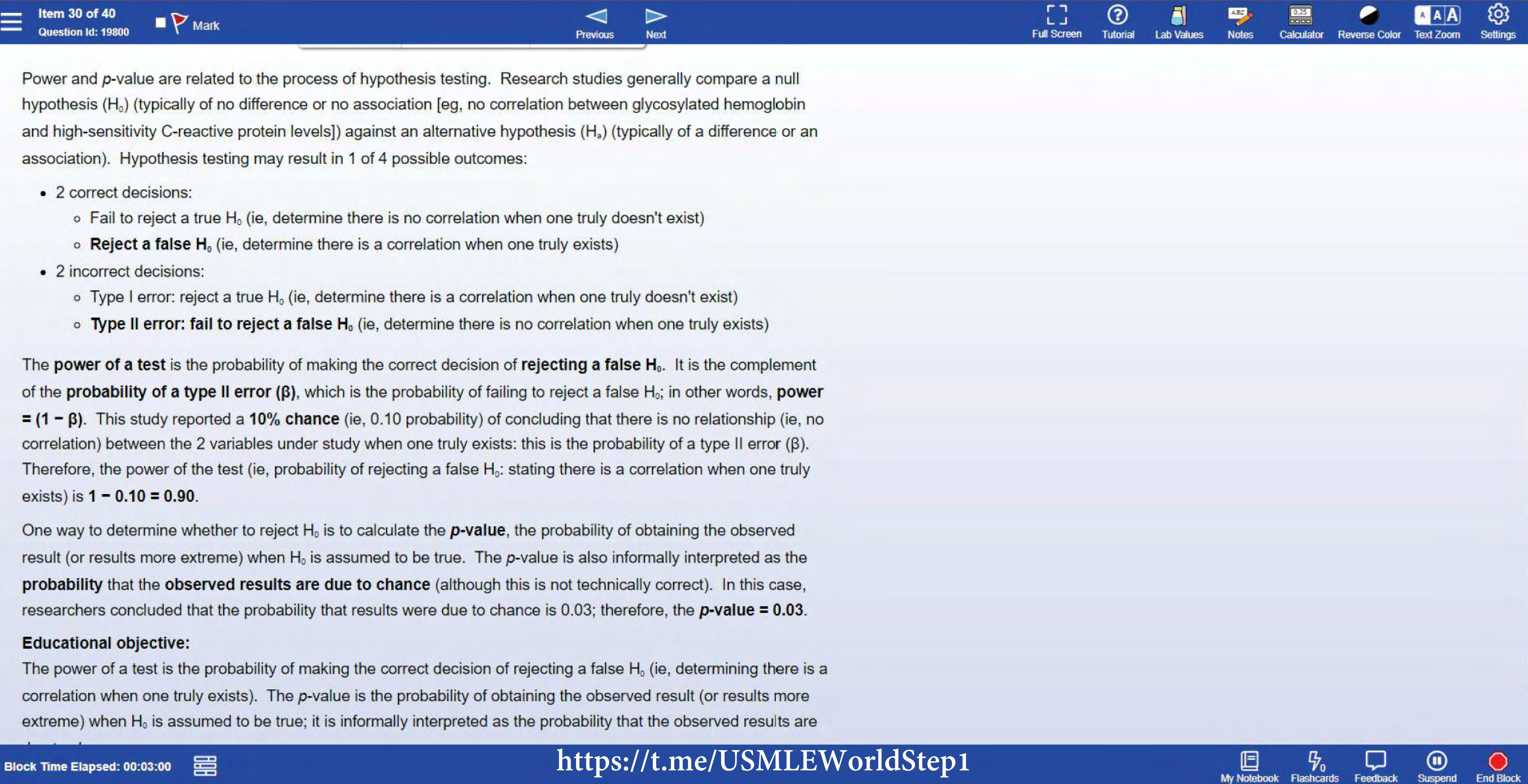


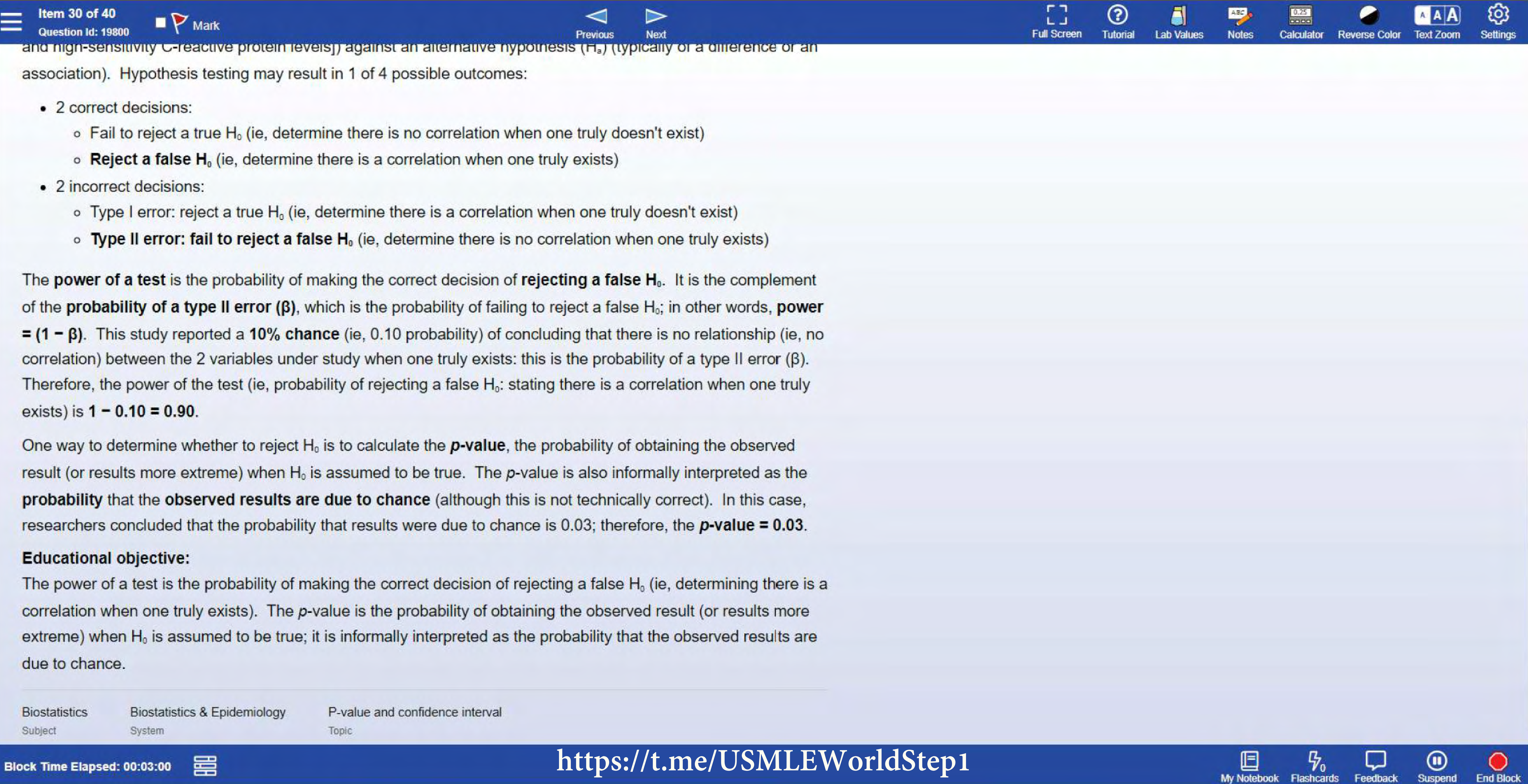
Power and *p*-value are related to the process of hypothesis testing. Research studies generally compare a null hypothesis (H_0) (typically of no difference or no association [eg, no correlation between glycosylated hemoglobin and high-sensitivity C-reactive protein levels]) against an alternative hypothesis (H_a) (typically of a difference or an association). Hypothesis testing may result in 1 of 4 possible outcomes:

- 2 correct decisions:
  - Fail to reject a true H_0 (ie, determine there is no correlation when one truly doesn't exist)
  - **Reject a false H_0** (ie, determine there is a correlation when one truly exists)
- 2 incorrect decisions:
  - Type I error: reject a true H_0 (ie, determine there is a correlation when one truly doesn't exist)
  - **Type II error: fail to reject a false H_0** (ie, determine there is no correlation when one truly exists)

The **power of a test** is the probability of making the correct decision of **rejecting a false H_0**. It is the complement of the **probability of a type II error (β)**, which is the probability of failing to reject a false H_0; in other words, **power = (1 − β)**. This study reported a **10% chance** (ie, 0.10 probability) of concluding that there is no relationship (ie, no correlation) between the 2 variables under study when one truly exists: this is the probability of a type II error (β). Therefore, the power of the test (ie, probability of rejecting a false H_0: stating there is a correlation when one truly exists) is **1 − 0.10 = 0.90**.

One way to determine whether to reject H_0 is to calculate the ***p*-value**, the probability of obtaining the observed result (or results more extreme) when H_0 is assumed to be true. The *p*-value is also informally interpreted as the **probability** that the **observed results are due to chance** (although this is not technically correct). In this case, researchers concluded that the probability that results were due to chance is 0.03; therefore, the ***p*-value = 0.03**.

Educational objective:
The power of a test is the probability of making the correct decision of rejecting a false H_0 (ie, determining there is a correlation when one truly exists). The *p*-value is the probability of obtaining the observed result (or results more extreme) when H_0 is assumed to be true; it is informally interpreted as the probability that the observed results are



and high-sensitivity C-reactive protein levels]) against an alternative hypothesis (H_a) (typically of a difference or an association). Hypothesis testing may result in 1 of 4 possible outcomes:

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  - Fail to reject a true H_0 (ie, determine there is no correlation when one truly doesn't exist)
  - **Reject a false H_0** (ie, determine there is a correlation when one truly exists)
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  - Type I error: reject a true H_0 (ie, determine there is a correlation when one truly doesn't exist)
  - **Type II error: fail to reject a false H_0** (ie, determine there is no correlation when one truly exists)

The **power of a test** is the probability of making the correct decision of **rejecting a false H_0**. It is the complement of the **probability of a type II error (β)**, which is the probability of failing to reject a false H_0; in other words, **power = (1 − β)**. This study reported a **10% chance** (ie, 0.10 probability) of concluding that there is no relationship (ie, no correlation) between the 2 variables under study when one truly exists: this is the probability of a type II error (β). Therefore, the power of the test (ie, probability of rejecting a false H_0: stating there is a correlation when one truly exists) is **1 − 0.10 = 0.90**.

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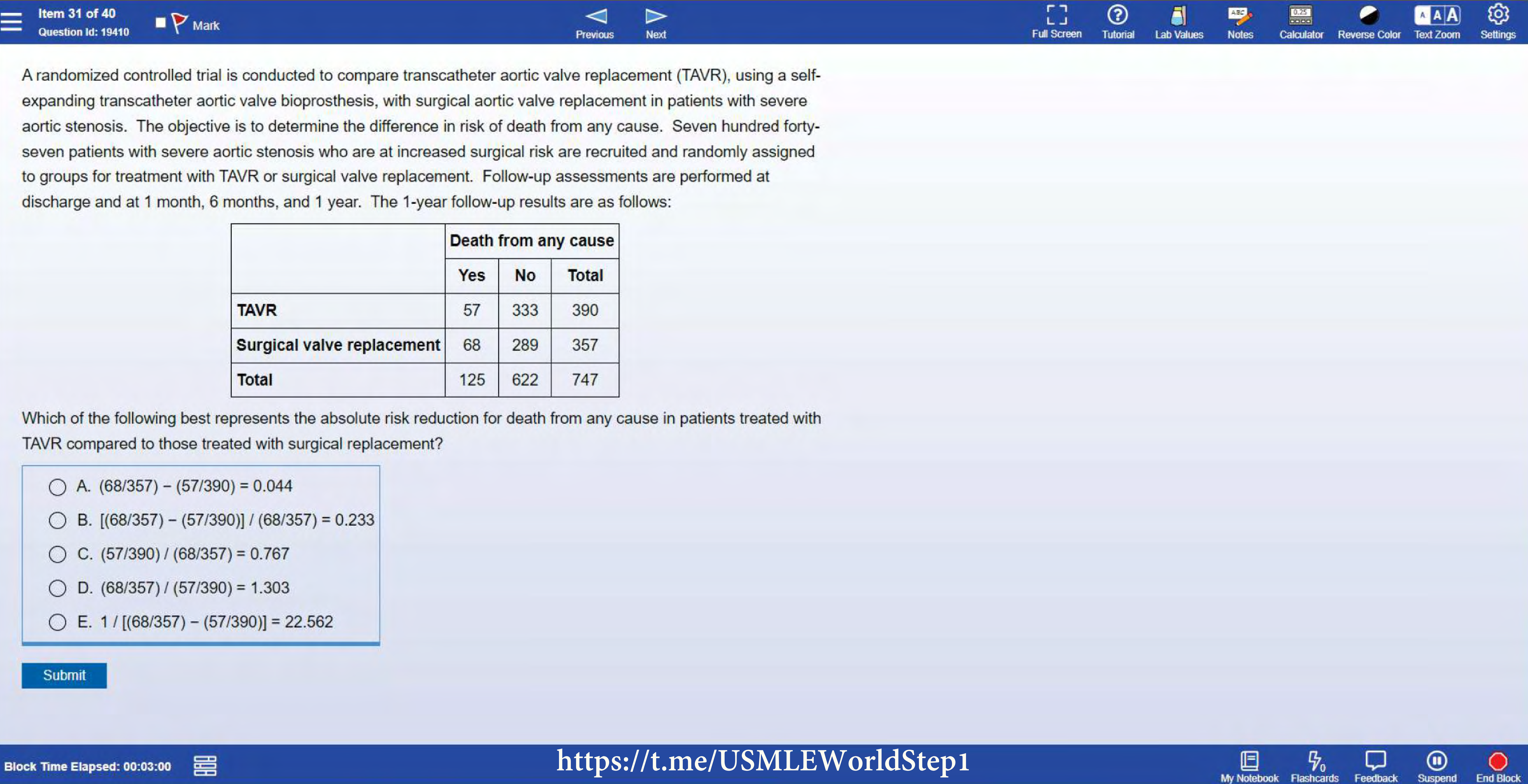
Educational objective:

The power of a test is the probability of making the correct decision of rejecting a false H_0 (ie, determining there is a correlation when one truly exists). The *p*-value is the probability of obtaining the observed result (or results more extreme) when H_0 is assumed to be true; it is informally interpreted as the probability that the observed results are due to chance.

Biostatistics	Biostatistics & Epidemiology	P-value and confidence interval
Subject	System	Topic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A randomized controlled trial is conducted to compare transcatheter aortic valve replacement (TAVR), using a self-expanding transcatheter aortic valve bioprosthesis, with surgical aortic valve replacement in patients with severe aortic stenosis. The objective is to determine the difference in risk of death from any cause. Seven hundred forty-seven patients with severe aortic stenosis who are at increased surgical risk are recruited and randomly assigned to groups for treatment with TAVR or surgical valve replacement. Follow-up assessments are performed at discharge and at 1 month, 6 months, and 1 year. The 1-year follow-up results are as follows:

	Death from any cause		
	Yes	**No**	**Total**
TAVR	57	333	390
Surgical valve replacement	68	289	357
Total	125	622	747

Which of the following best represents the absolute risk reduction for death from any cause in patients treated with TAVR compared to those treated with surgical replacement?

○ A. (68/357) − (57/390) = 0.044

○ B. [(68/357) − (57/390)] / (68/357) = 0.233

○ C. (57/390) / (68/357) = 0.767

○ D. (68/357) / (57/390) = 1.303

○ E. 1 / [(68/357) − (57/390)] = 22.562

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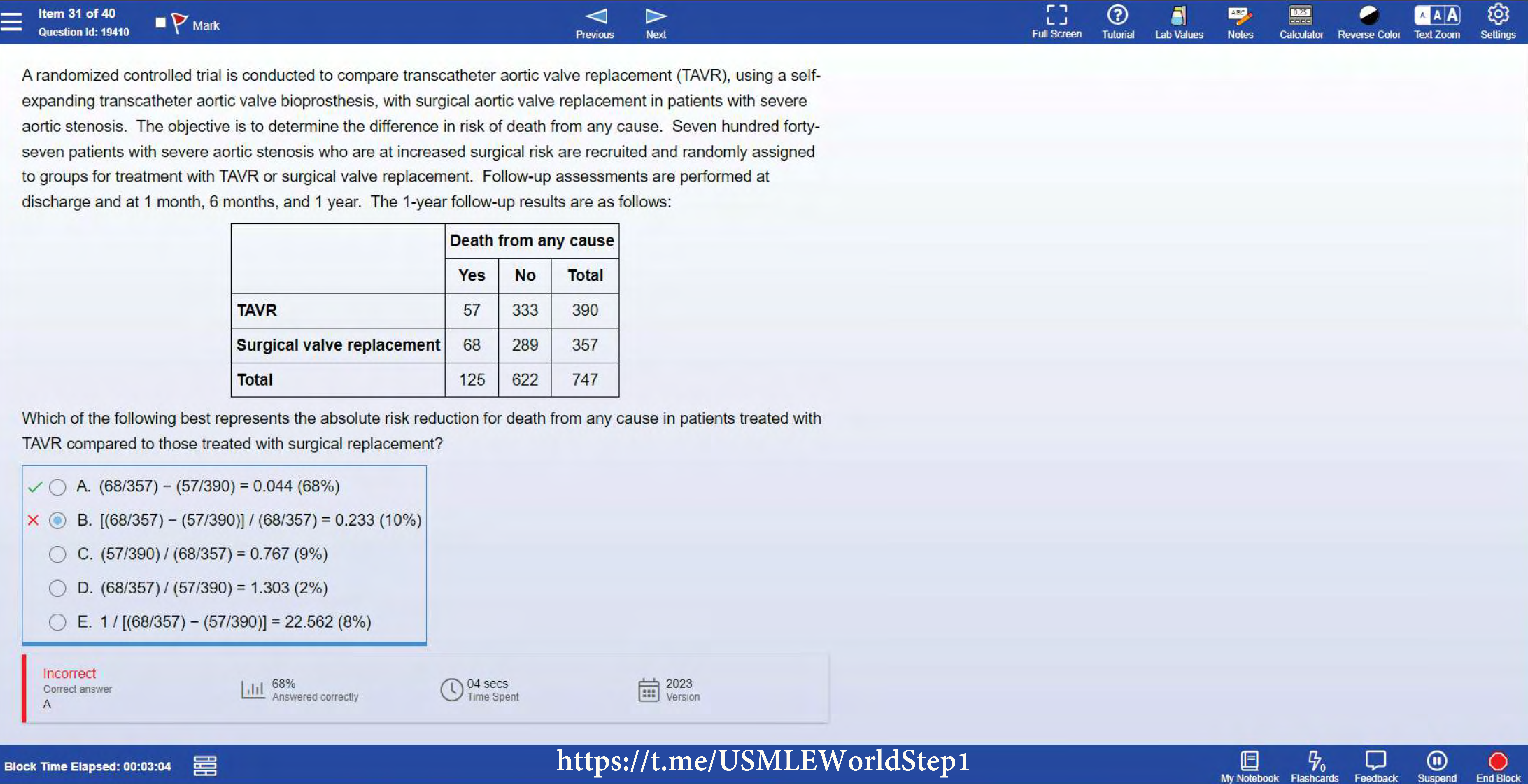

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	Yes	**No**	**Total**
TAVR	57	333	390
Surgical valve replacement	68	289	357
Total	125	622	747

Which of the following best represents the absolute risk reduction for death from any cause in patients treated with TAVR compared to those treated with surgical replacement?

✓ ○ A. (68/357) − (57/390) = 0.044 (68%)

✗ ● B. [(68/357) − (57/390)] / (68/357) = 0.233 (10%)

○ C. (57/390) / (68/357) = 0.767 (9%)

○ D. (68/357) / (57/390) = 1.303 (2%)

○ E. 1 / [(68/357) − (57/390)] = 22.562 (8%)

Incorrect
Correct answer
A

68%
Answered correctly

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Explanation

Absolute risk reduction (ARR) describes the difference in risk of an unfavorable outcome between the treatment group (eg, new treatment) and the control group (eg, standard treatment):

ARR = $(\text{Risk}_{\text{control}} - \text{Risk}_{\text{treatment}})$

In this example, $\textbf{Risk}_{\text{control}}$ is the risk of death from any cause in the group treated with surgical aortic valve replacement and is determined by dividing the number of deaths in that group (68) by the total number of patients in that group (357). $\textbf{Risk}_{\text{treatment}}$ is the risk of death from any cause in the group treated with transcatheter aortic valve replacement (TAVR) and is determined by dividing 57 by 390. Therefore, the ARR for death from any cause in patients treated with TAVR compared to those treated with surgical replacement is calculated as follows:

ARR = (68/357) − (57/390) = 0.044

ARR can be used to determine the number needed to treat (NNT), calculated as:

NNT = 1 / ARR

NNT is the number of patients who need to be treated with a treatment (eg, TAVR) to prevent 1 additional negative event (eg, death from any cause) when compared to a control group (eg, surgical replacement). A lower NNT indicates a more effective treatment because fewer patients need to be treated to prevent 1 additional negative outcome. In this example, the approximate NNT with TAVR to prevent 1 additional death from any cause is:

NNT = 1 / [(68/357) – (57/390)] = 22.562 **(Choice E)**

(Choice B) [(68/357) – (57/390)] / (68/357) = 0.233 represents the relative risk reduction (RRR) for death from any cause in the TAVR group compared to the surgical replacement group: RRR = $(\text{Risk}_{\text{control}} - \text{Risk}_{\text{treatment}}) / \text{Risk}_{\text{control}}$. Unlike ARR, which quantifies the absolute difference in risk between the groups, RRR describes the difference in risk between the groups as a proportion of baseline risk (ie, risk in the control group).

(Choices C and D) Switching the numerator and denominator changes the interpretation of the relative risk (RR,

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(Choice B) [(68/357) − (57/390)] / (68/357) = 0.233 represents the relative risk reduction (RRR) for death from any cause in the TAVR group compared to the surgical replacement group: RRR = ($\text{Risk}_{\text{control}}$ − $\text{Risk}_{\text{treatment}}$) / $\text{Risk}_{\text{control}}$. Unlike ARR, which quantifies the absolute difference in risk between the groups, RRR describes the difference in risk between the groups as a proportion of baseline risk (ie, risk in the control group).

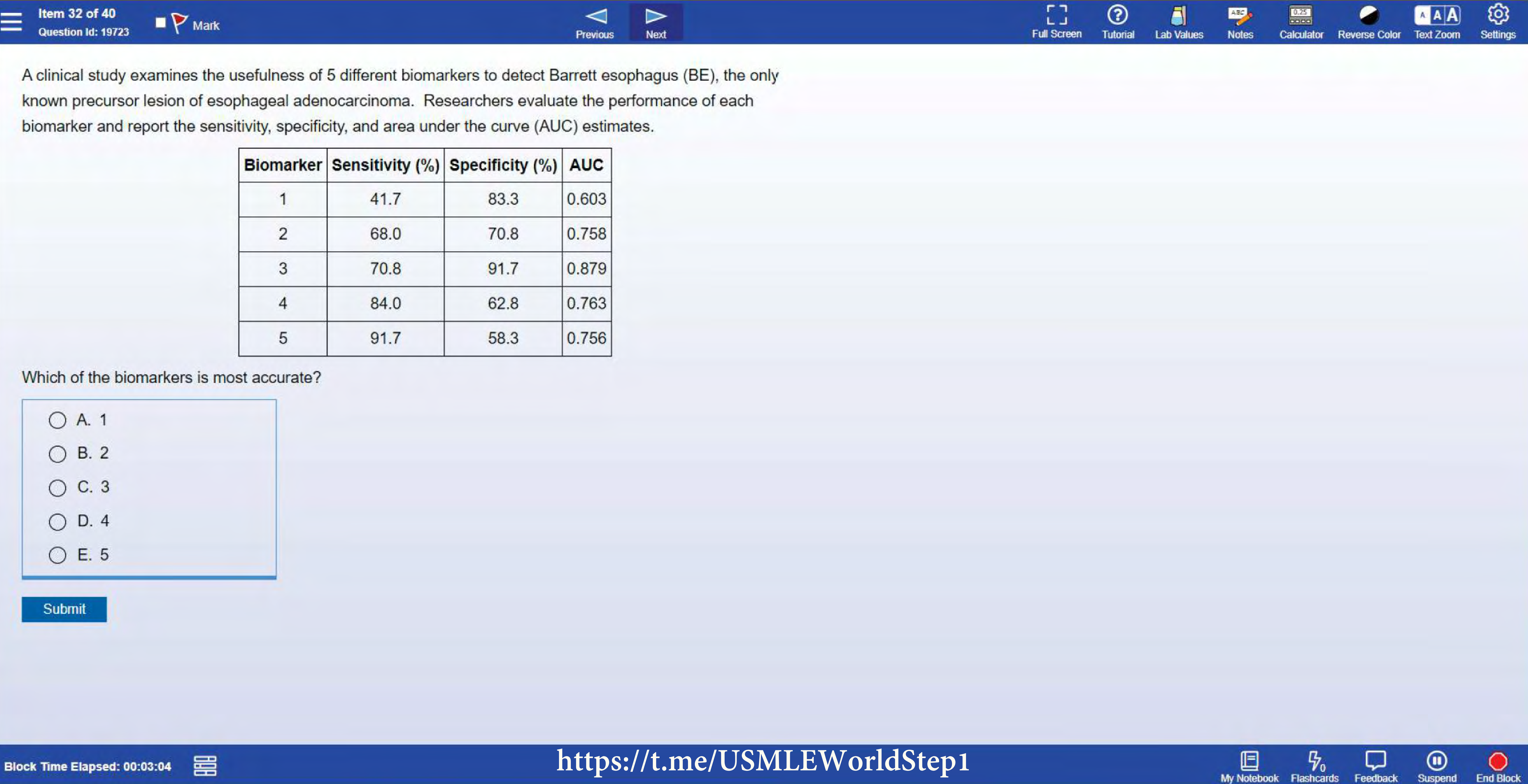
(Choices C and D) Switching the numerator and denominator changes the interpretation of the relative risk (RR, the ratio of the probability of an event occuring in one group compared to the other group). In this example, (57/390) / (68/357) represents the RR of death from any cause in the TAVR group compared to the surgical replacement group; (68/357) / (57/390) represents the RR of death from any cause in the surgical replacement group compared to the TAVR group.

Educational objective:

Absolute risk reduction (ARR) describes the difference in risk between control and treatment groups. It is calculated as follows: ARR = ($\text{Risk}_{\text{control}}$ − $\text{Risk}_{\text{treatment}}$).

References

- Measures of effect in epidemiological research.
- Measures of effect: relative risks, odds ratios, risk difference, and "number needed to treat."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A clinical study examines the usefulness of 5 different biomarkers to detect Barrett esophagus (BE), the only known precursor lesion of esophageal adenocarcinoma. Researchers evaluate the performance of each biomarker and report the sensitivity, specificity, and area under the curve (AUC) estimates.

Biomarker	Sensitivity (%)	Specificity (%)	AUC
1	41.7	83.3	0.603
2	68.0	70.8	0.758
3	70.8	91.7	0.879
4	84.0	62.8	0.763
5	91.7	58.3	0.756

Which of the biomarkers is most accurate?

○ A. 1

○ B. 2

○ C. 3

○ D. 4

○ E. 5

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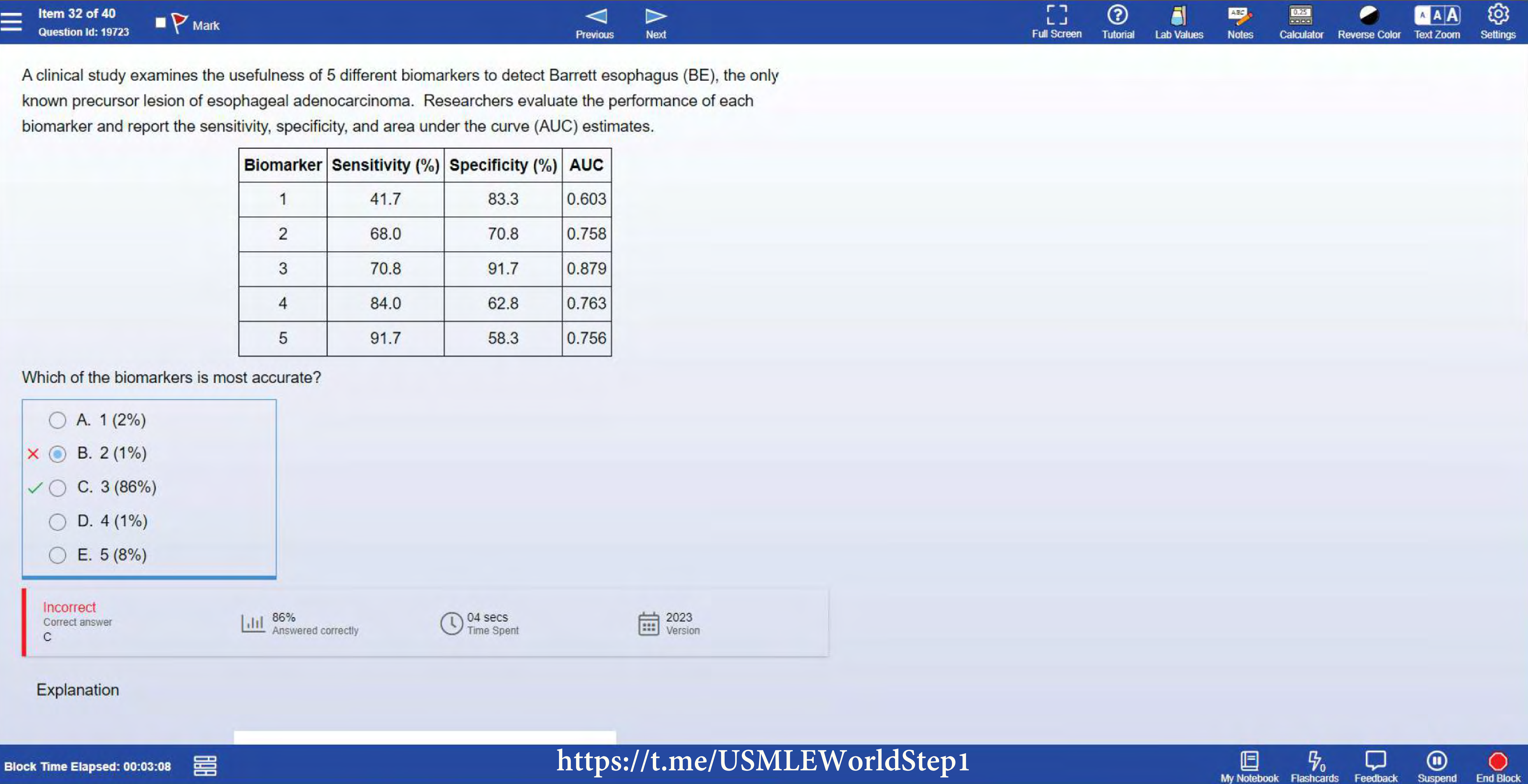
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2	68.0	70.8	0.758
3	70.8	91.7	0.879
4	84.0	62.8	0.763
5	91.7	58.3	0.756

Which of the biomarkers is most accurate?

○ A. 1 (2%)
✗ ● B. 2 (1%)
✓ ○ C. 3 (86%)
○ D. 4 (1%)
○ E. 5 (8%)

Incorrect
Correct answer
C

86%
Answered correctly

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Explanation

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Interpretation of areas under the ROC curve

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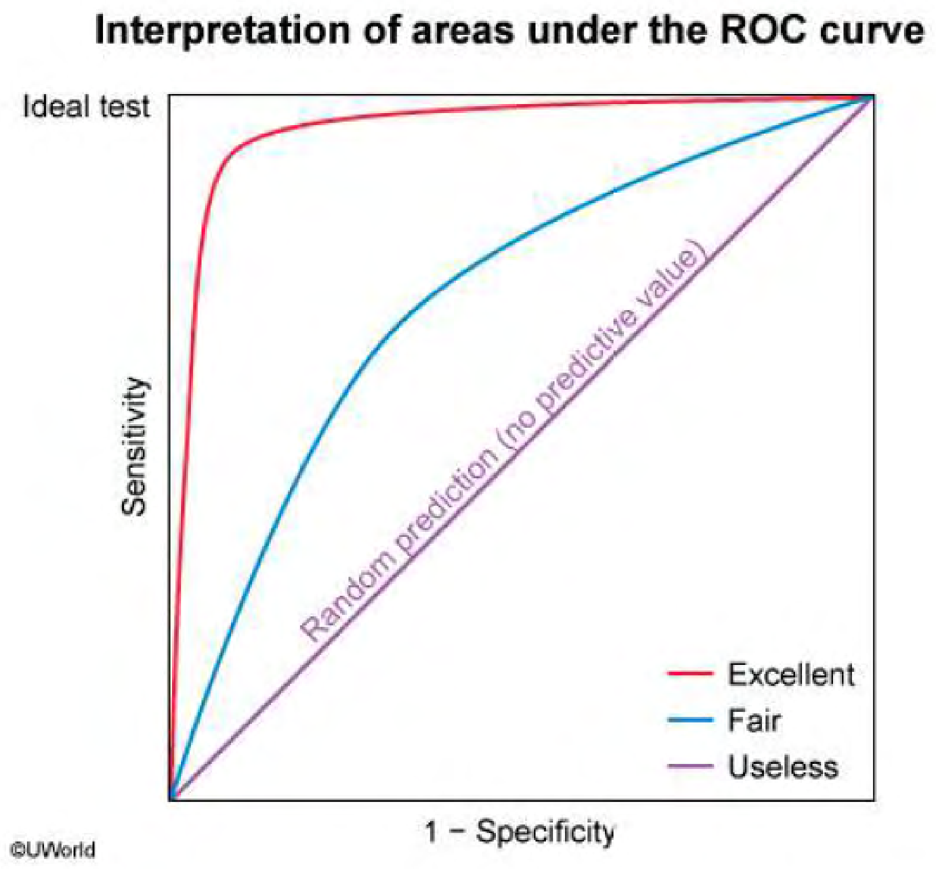

Interpretation of areas under the ROC curve

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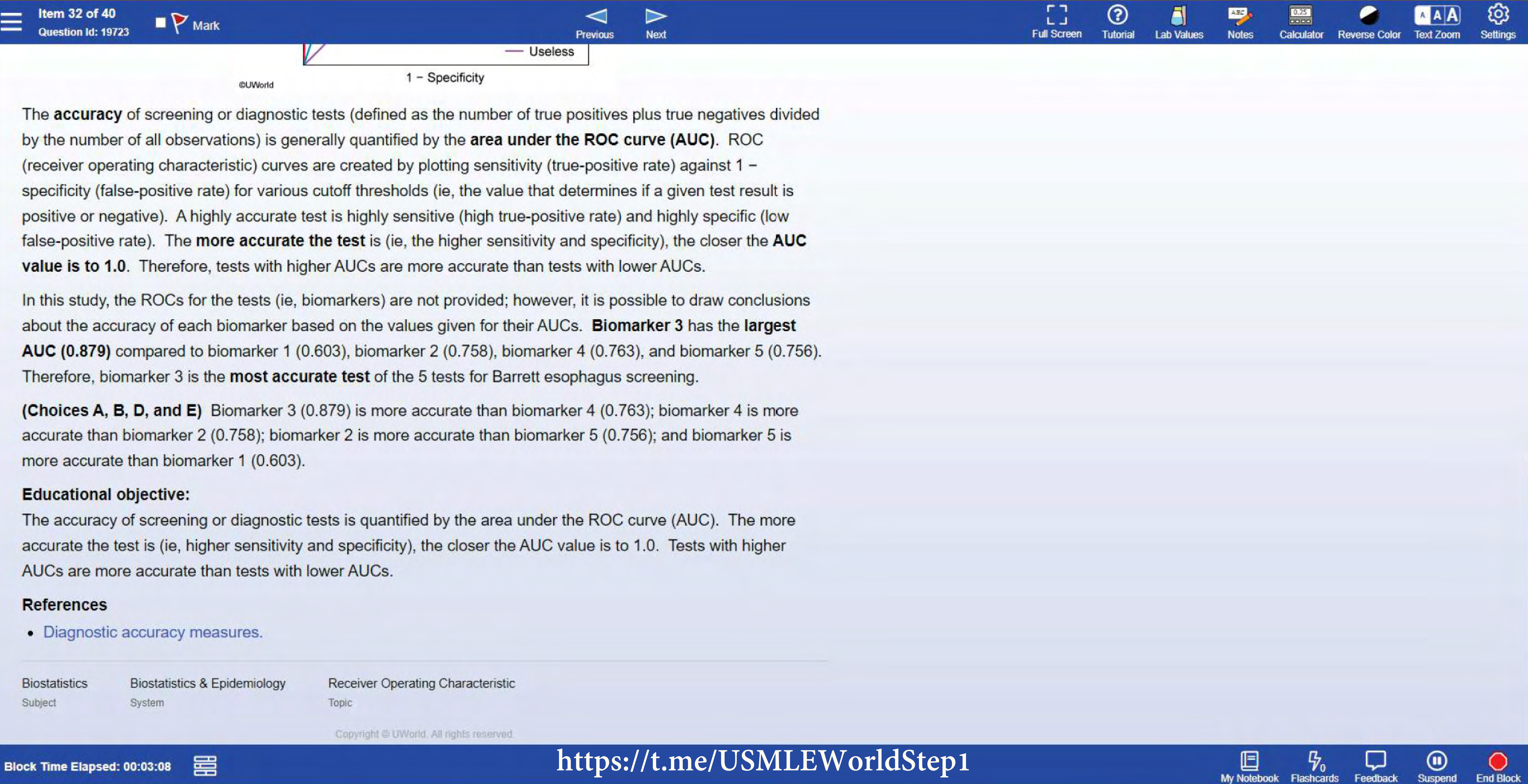
(Choices A, B, D, and E) Biomarker 3 (0.879) is more accurate than biomarker 4 (0.763); biomarker 4 is more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The **accuracy** of screening or diagnostic tests (defined as the number of true positives plus true negatives divided by the number of all observations) is generally quantified by the **area under the ROC curve (AUC)**. ROC (receiver operating characteristic) curves are created by plotting sensitivity (true-positive rate) against 1 – specificity (false-positive rate) for various cutoff thresholds (ie, the value that determines if a given test result is positive or negative). A highly accurate test is highly sensitive (high true-positive rate) and highly specific (low false-positive rate). The **more accurate the test** is (ie, the higher sensitivity and specificity), the closer the **AUC value is to 1.0**. Therefore, tests with higher AUCs are more accurate than tests with lower AUCs.

In this study, the ROCs for the tests (ie, biomarkers) are not provided; however, it is possible to draw conclusions about the accuracy of each biomarker based on the values given for their AUCs. **Biomarker 3** has the **largest AUC (0.879)** compared to biomarker 1 (0.603), biomarker 2 (0.758), biomarker 4 (0.763), and biomarker 5 (0.756). Therefore, biomarker 3 is the **most accurate test** of the 5 tests for Barrett esophagus screening.

(Choices A, B, D, and E) Biomarker 3 (0.879) is more accurate than biomarker 4 (0.763); biomarker 4 is more accurate than biomarker 2 (0.758); biomarker 2 is more accurate than biomarker 5 (0.756); and biomarker 5 is more accurate than biomarker 1 (0.603).

Educational objective:

The accuracy of screening or diagnostic tests is quantified by the area under the ROC curve (AUC). The more accurate the test is (ie, higher sensitivity and specificity), the closer the AUC value is to 1.0. Tests with higher AUCs are more accurate than tests with lower AUCs.

References

- Diagnostic accuracy measures.

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Subject

Biostatistics & Epidemiology
System

Receiver Operating Characteristic
Topic

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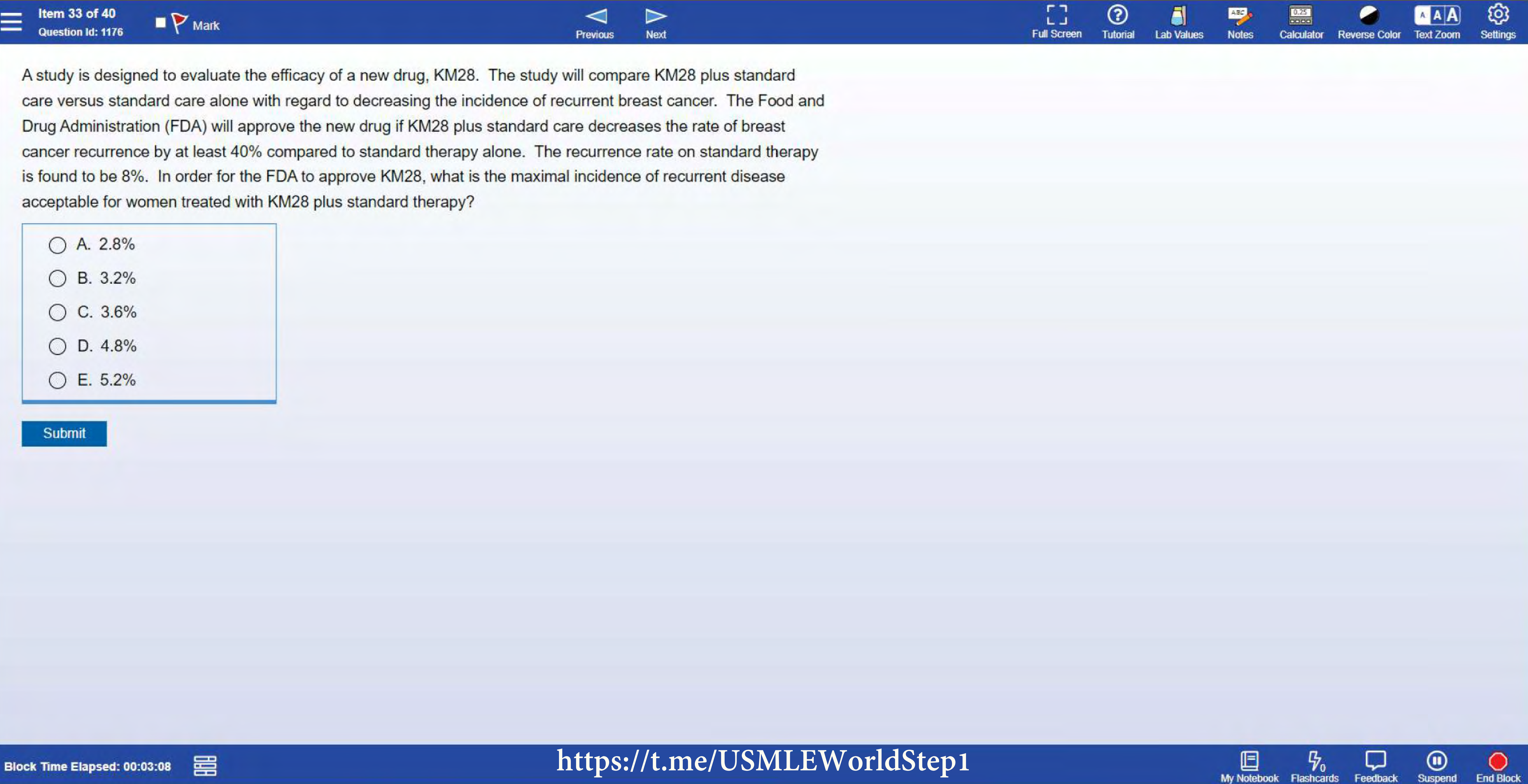
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A study is designed to evaluate the efficacy of a new drug, KM28. The study will compare KM28 plus standard care versus standard care alone with regard to decreasing the incidence of recurrent breast cancer. The Food and Drug Administration (FDA) will approve the new drug if KM28 plus standard care decreases the rate of breast cancer recurrence by at least 40% compared to standard therapy alone. The recurrence rate on standard therapy is found to be 8%. In order for the FDA to approve KM28, what is the maximal incidence of recurrent disease acceptable for women treated with KM28 plus standard therapy?

○ A. 2.8%
○ B. 3.2%
○ C. 3.6%
○ D. 4.8%
○ E. 5.2%

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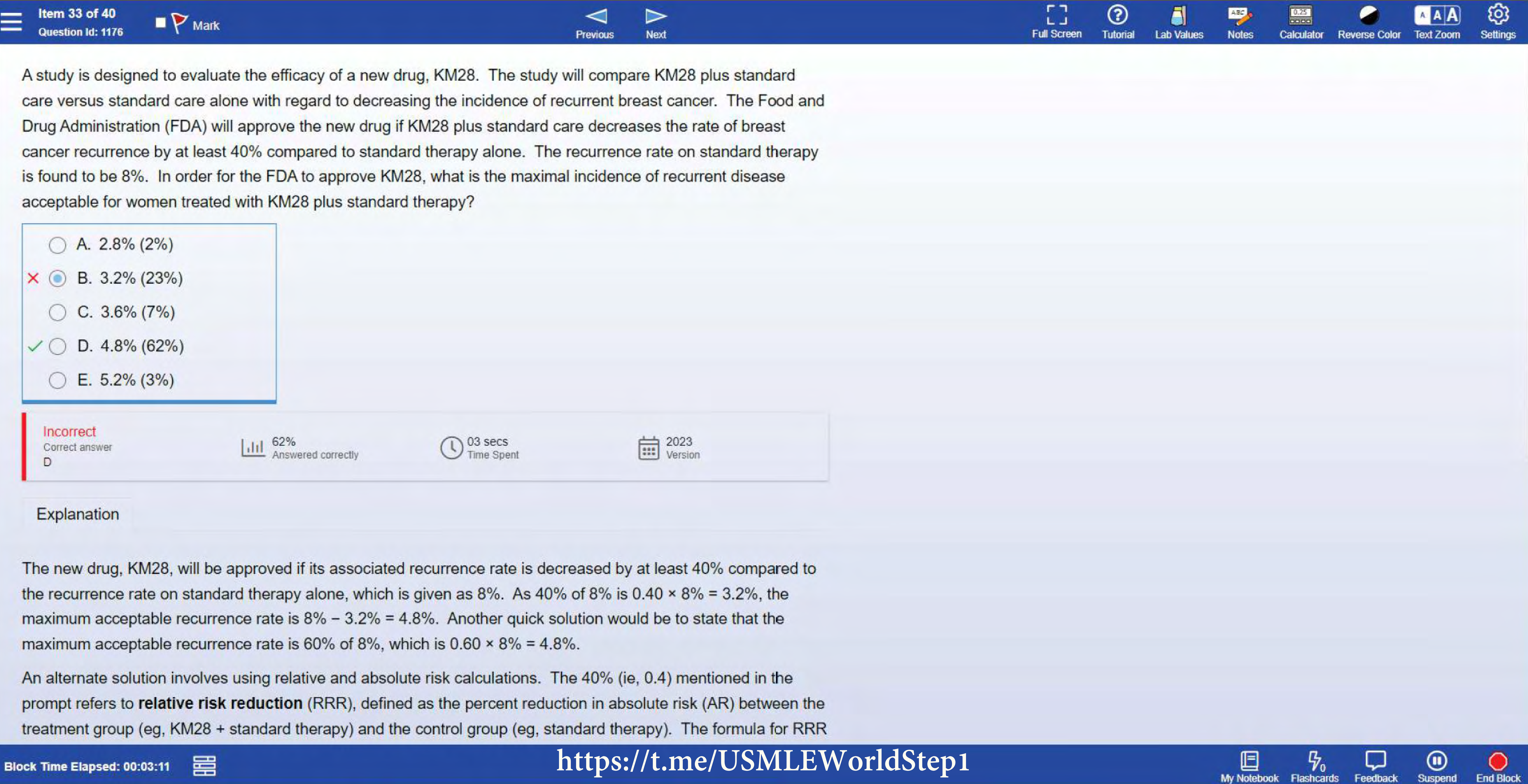
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- ○ A. 2.8% (2%)
- ✗ ● B. 3.2% (23%)
- ○ C. 3.6% (7%)
- ✓ ○ D. 4.8% (62%)
- ○ E. 5.2% (3%)

Incorrect
Correct answer
D

62%
Answered correctly

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Explanation

The new drug, KM28, will be approved if its associated recurrence rate is decreased by at least 40% compared to the recurrence rate on standard therapy alone, which is given as 8%. As 40% of 8% is 0.40 × 8% = 3.2%, the maximum acceptable recurrence rate is 8% − 3.2% = 4.8%. Another quick solution would be to state that the maximum acceptable recurrence rate is 60% of 8%, which is 0.60 × 8% = 4.8%.

An alternate solution involves using relative and absolute risk calculations. The 40% (ie, 0.4) mentioned in the prompt refers to **relative risk reduction** (RRR), defined as the percent reduction in absolute risk (AR) between the treatment group (eg, KM28 + standard therapy) and the control group (eg, standard therapy). The formula for RRR

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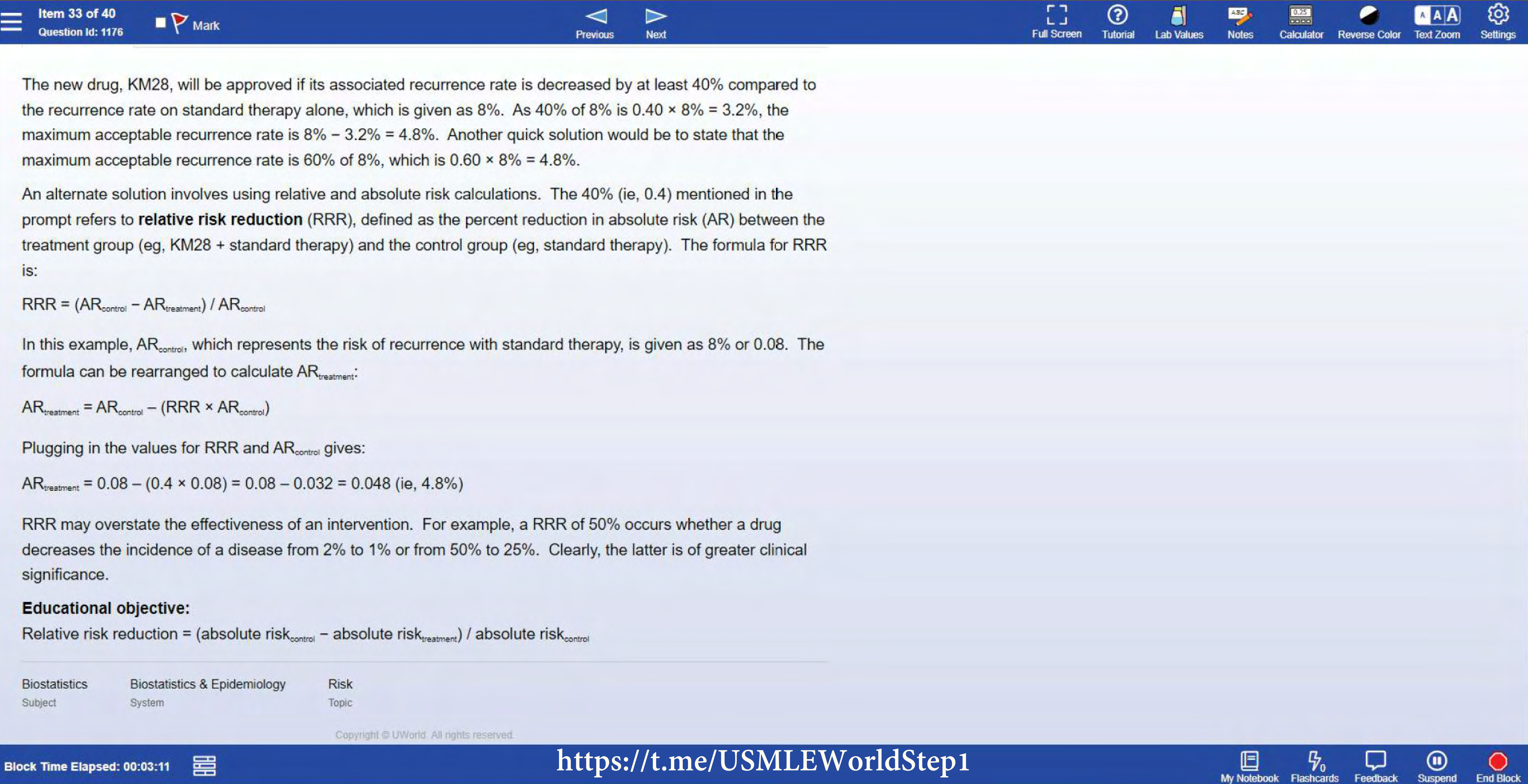
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The new drug, KM28, will be approved if its associated recurrence rate is decreased by at least 40% compared to the recurrence rate on standard therapy alone, which is given as 8%. As 40% of 8% is 0.40 × 8% = 3.2%, the maximum acceptable recurrence rate is 8% − 3.2% = 4.8%. Another quick solution would be to state that the maximum acceptable recurrence rate is 60% of 8%, which is 0.60 × 8% = 4.8%.

An alternate solution involves using relative and absolute risk calculations. The 40% (ie, 0.4) mentioned in the prompt refers to **relative risk reduction** (RRR), defined as the percent reduction in absolute risk (AR) between the treatment group (eg, KM28 + standard therapy) and the control group (eg, standard therapy). The formula for RRR is:

$RRR = (AR_{control} - AR_{treatment}) / AR_{control}$

In this example, $AR_{control}$, which represents the risk of recurrence with standard therapy, is given as 8% or 0.08. The formula can be rearranged to calculate $AR_{treatment}$:

$AR_{treatment} = AR_{control} - (RRR \times AR_{control})$

Plugging in the values for RRR and $AR_{control}$ gives:

$AR_{treatment} = 0.08 - (0.4 \times 0.08) = 0.08 - 0.032 = 0.048$ (ie, 4.8%)

RRR may overstate the effectiveness of an intervention. For example, a RRR of 50% occurs whether a drug decreases the incidence of a disease from 2% to 1% or from 50% to 25%. Clearly, the latter is of greater clinical significance.

Educational objective:

Relative risk reduction = (absolute risk$_{control}$ − absolute risk$_{treatment}$) / absolute risk$_{control}$

Biostatistics	Biostatistics & Epidemiology	Risk
Subject	System	Topic

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A study is designed to describe the manifestations of coronavirus disease 2019 (COVID-19) on imaging studies, particularly on computerized tomography (CT) scans. Eleven patients with COVID-19 are recruited for the study, and their CT findings are studied and characterized. Which of the following best describes this study design?

○ A. Case-control
○ B. Case series
○ C. Clinical trial
○ D. Cohort
○ E. Cross-sectional

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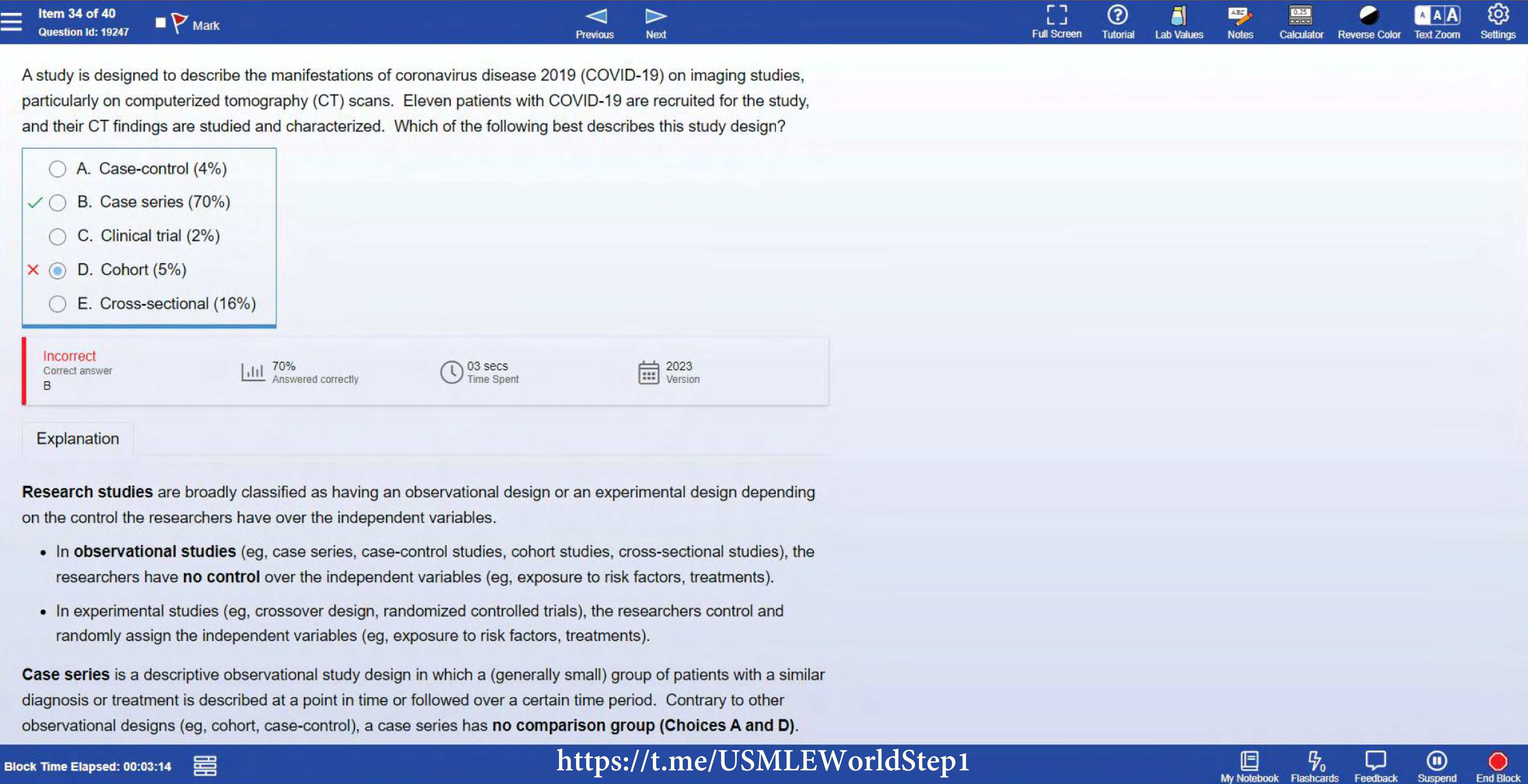
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A study is designed to describe the manifestations of coronavirus disease 2019 (COVID-19) on imaging studies, particularly on computerized tomography (CT) scans. Eleven patients with COVID-19 are recruited for the study, and their CT findings are studied and characterized. Which of the following best describes this study design?

○ A. Case-control (4%)

✓ ○ B. Case series (70%)

○ C. Clinical trial (2%)

✗ ● D. Cohort (5%)

○ E. Cross-sectional (16%)

Incorrect
Correct answer
B

70%
Answered correctly

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Explanation

Research studies are broadly classified as having an observational design or an experimental design depending on the control the researchers have over the independent variables.

- In **observational studies** (eg, case series, case-control studies, cohort studies, cross-sectional studies), the researchers have **no control** over the independent variables (eg, exposure to risk factors, treatments).
- In experimental studies (eg, crossover design, randomized controlled trials), the researchers control and randomly assign the independent variables (eg, exposure to risk factors, treatments).

Case series is a descriptive observational study design in which a (generally small) group of patients with a similar diagnosis or treatment is described at a point in time or followed over a certain time period. Contrary to other observational designs (eg, cohort, case-control), a case series has **no comparison group (Choices A and D)**.

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Research studies are broadly classified as having an observational design or an experimental design depending on the control the researchers have over the independent variables.

- In **observational studies** (eg, case series, case-control studies, cohort studies, cross-sectional studies), the researchers have **no control** over the independent variables (eg, exposure to risk factors, treatments).
- In experimental studies (eg, crossover design, randomized controlled trials), the researchers control and randomly assign the independent variables (eg, exposure to risk factors, treatments).

Case series is a descriptive observational study design in which a (generally small) group of patients with a similar diagnosis or treatment is described at a point in time or followed over a certain time period. Contrary to other observational designs (eg, cohort, case-control), a case series has **no comparison group (Choices A and D)**. For this reason, a case series cannot establish associations between risk factors (eg, treatments) and outcomes (eg, diseases).

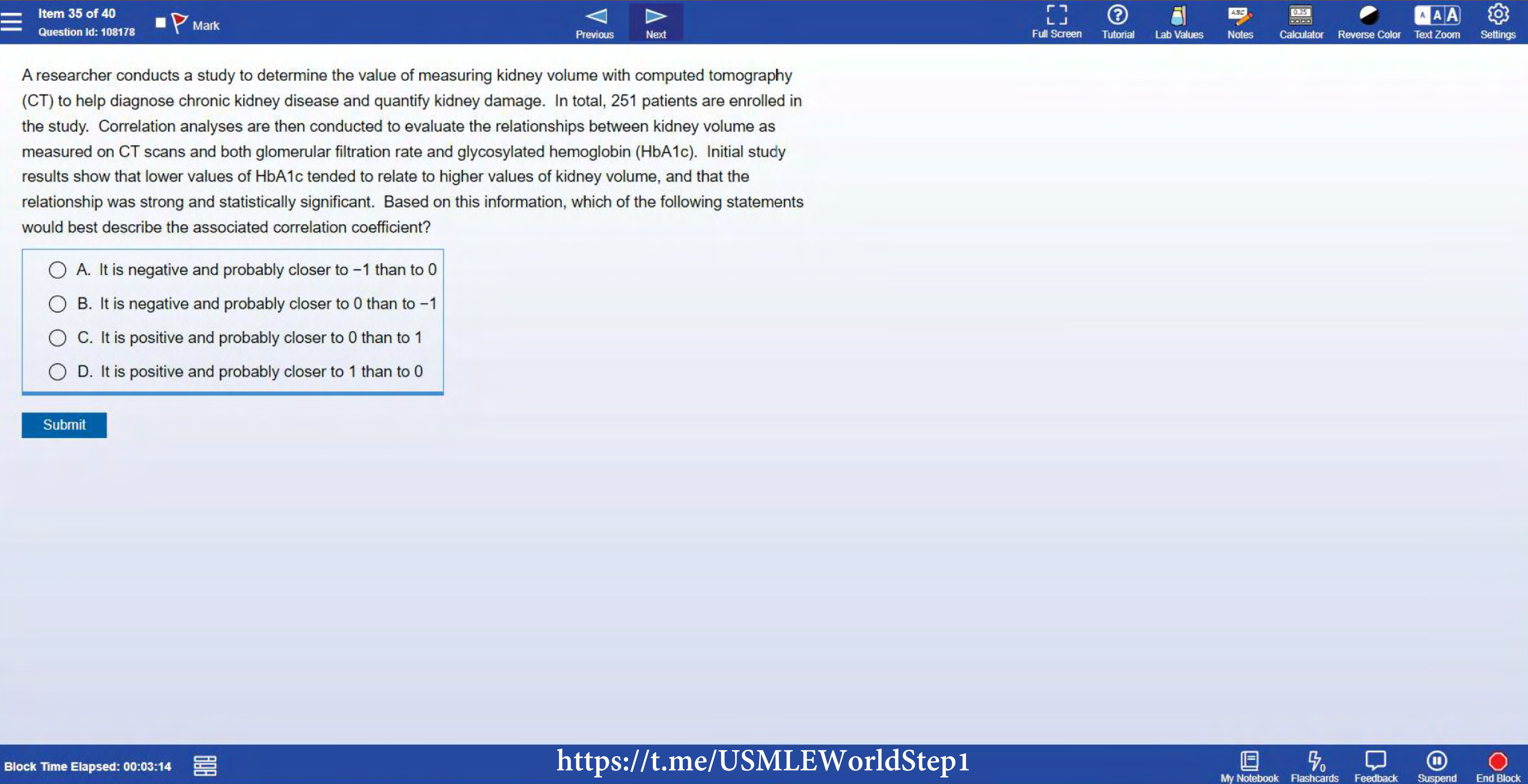
In this example, the CT scan findings of 11 patients with coronavirus disease 2019 (COVID-19) are being studied. The study has no control group; therefore, it can only describe COVID-19 manifestations on imaging studies.

(Choice C) A clinical trial is an experimental study in which patients are prospectively assigned to ≥2 interventions (often including a placebo or control treatment) to evaluate the effects of those interventions on outcomes of interest.

(Choice E) A cross-sectional study is an observational study that assesses a population of interest (eg, all women of reproductive age) at a single point in time; it can be used to estimate disease prevalence and association with risk factors of interest. However, it is not used to characterize disease findings because subjects are not selected based on the presence of disease.

Educational objective:

A case series is a descriptive observational study design in which a group of patients with a similar diagnosis or treatment is described at a point in time or followed over a certain period. This study design has no comparison group; therefore, it cannot establish associations between risk factors (eg, treatments) and outcomes (eg, diseases).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A researcher conducts a study to determine the value of measuring kidney volume with computed tomography (CT) to help diagnose chronic kidney disease and quantify kidney damage. In total, 251 patients are enrolled in the study. Correlation analyses are then conducted to evaluate the relationships between kidney volume as measured on CT scans and both glomerular filtration rate and glycosylated hemoglobin (HbA1c). Initial study results show that lower values of HbA1c tended to relate to higher values of kidney volume, and that the relationship was strong and statistically significant. Based on this information, which of the following statements would best describe the associated correlation coefficient?

○ A. It is negative and probably closer to −1 than to 0
○ B. It is negative and probably closer to 0 than to −1
○ C. It is positive and probably closer to 0 than to 1
○ D. It is positive and probably closer to 1 than to 0

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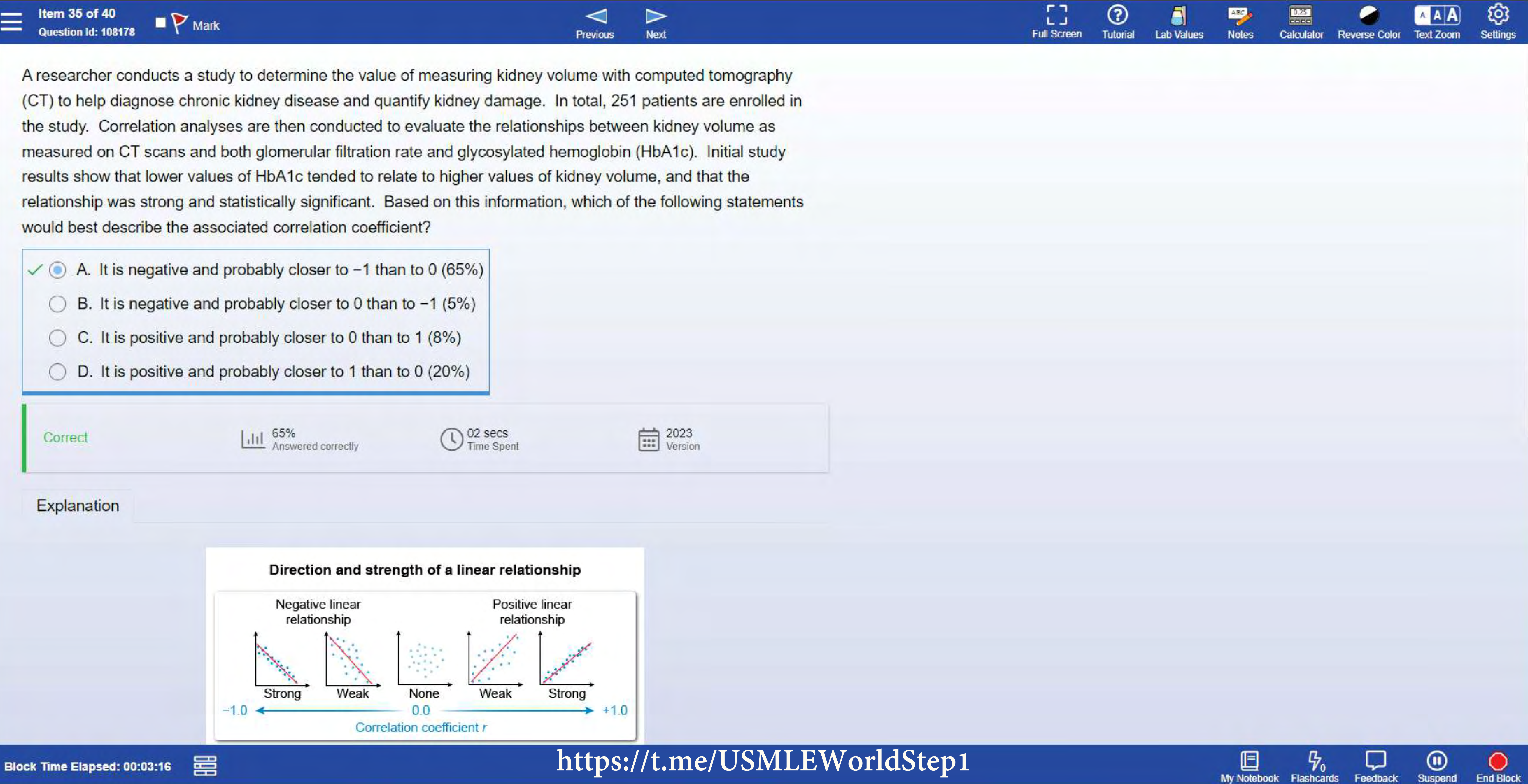
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A researcher conducts a study to determine the value of measuring kidney volume with computed tomography (CT) to help diagnose chronic kidney disease and quantify kidney damage. In total, 251 patients are enrolled in the study. Correlation analyses are then conducted to evaluate the relationships between kidney volume as measured on CT scans and both glomerular filtration rate and glycosylated hemoglobin (HbA1c). Initial study results show that lower values of HbA1c tended to relate to higher values of kidney volume, and that the relationship was strong and statistically significant. Based on this information, which of the following statements would best describe the associated correlation coefficient?

✓ ● A. It is negative and probably closer to −1 than to 0 (65%)

○ B. It is negative and probably closer to 0 than to −1 (5%)

○ C. It is positive and probably closer to 0 than to 1 (8%)

○ D. It is positive and probably closer to 1 than to 0 (20%)

Correct

65% Answered correctly

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Explanation

Direction and strength of a linear relationship

Negative linear relationship
Positive linear relationship
Strong
Weak
None
Weak
Strong
−1.0
0.0
+1.0
Correlation coefficient *r*

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would best describe the associated correlation coefficient?

✓ ●

○

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○

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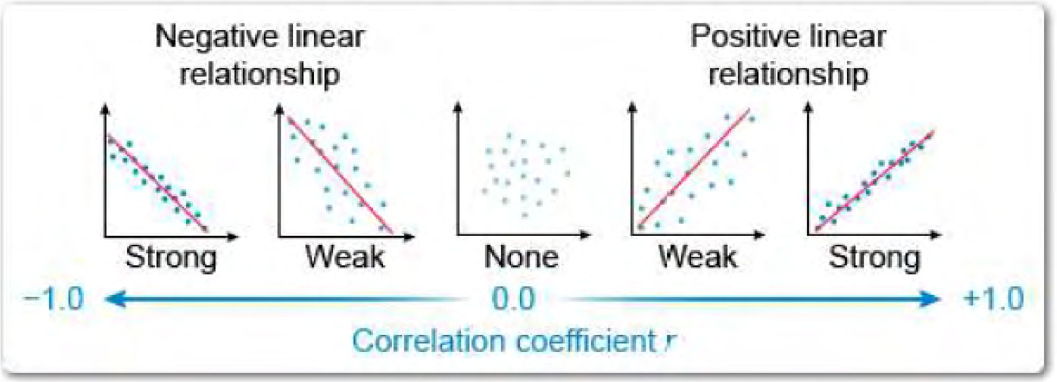
Direction and strength of a linear relationship


Negative linear relationship
Positive linear relationship
Strong
Weak
None
Weak
Strong
−1.0
0.0
+1.0
Correlation coefficient r

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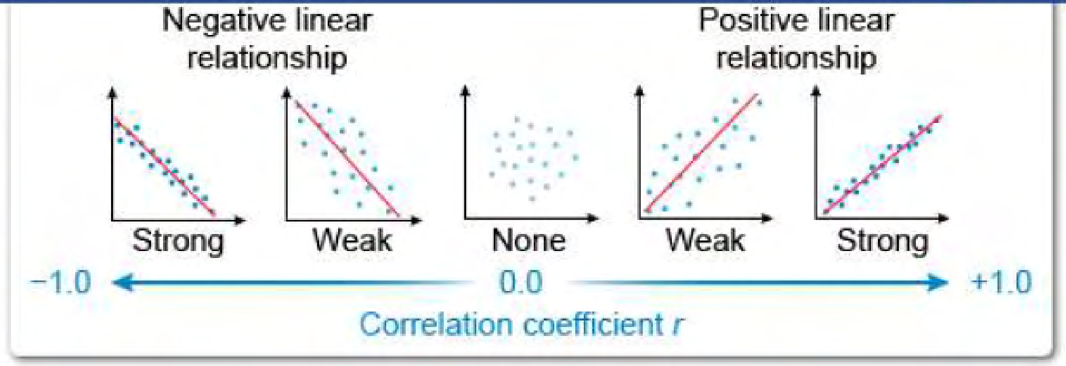
variable.

- r < 0 (ie, **negative**) indicates an inverse relationship, so as **one variable increases, the other variable**


Negative linear relationship
Positive linear relationship
Strong
Weak
None
Weak
Strong
−1.0
0.0
+1.0
Correlation coefficient r

The **correlation coefficient** *r* describes the linear relationship between 2 quantitative variables by its direction (negative or positive) and its strength (a value closer to −1 or 1 indicates a stronger relationship).

- $r > 0$ (ie, **positive**) indicates a direct relationship, so **both variables increase (or decrease) together**. This means that higher (or lower) values of one variable tend to relate to higher (or lower) values of the other variable.
- $r < 0$ (ie, **negative**) indicates an inverse relationship, so as **one variable increases, the other variable decreases**. This means that higher values of one variable tend to relate to lower values of the other variable, and vice versa.

In this study, lower values of HbA1c tended to relate to higher values of kidney volume. This means that one variable increased as the other variable decreased, so the correlation coefficient must be negative **(Choices C and D)**. Because the relationship was described as **strong**, the correlation coefficient must be **closer to −1** than to 0 **(Choice B)**.

Educational objective:
The correlation coefficient *r* describes the direction (negative or positive) and the strength (a value closer to −1 or 1 indicates a stronger relationship) of the linear relationship between 2 quantitative variables. It does not necessarily imply causality.

Biostatistics	Biostatistics & Epidemiology	Correlation coefficient
Subject	System	Topic

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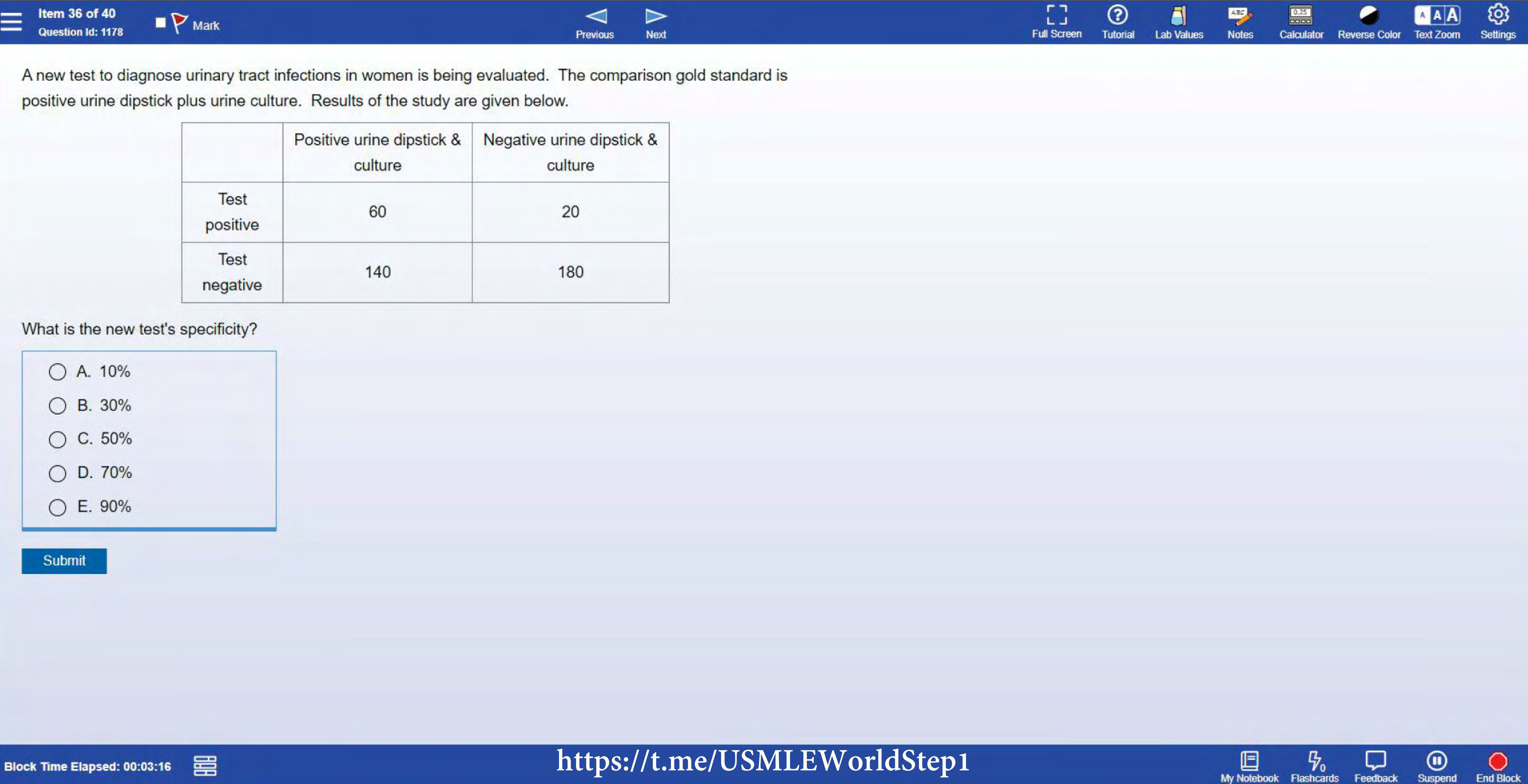
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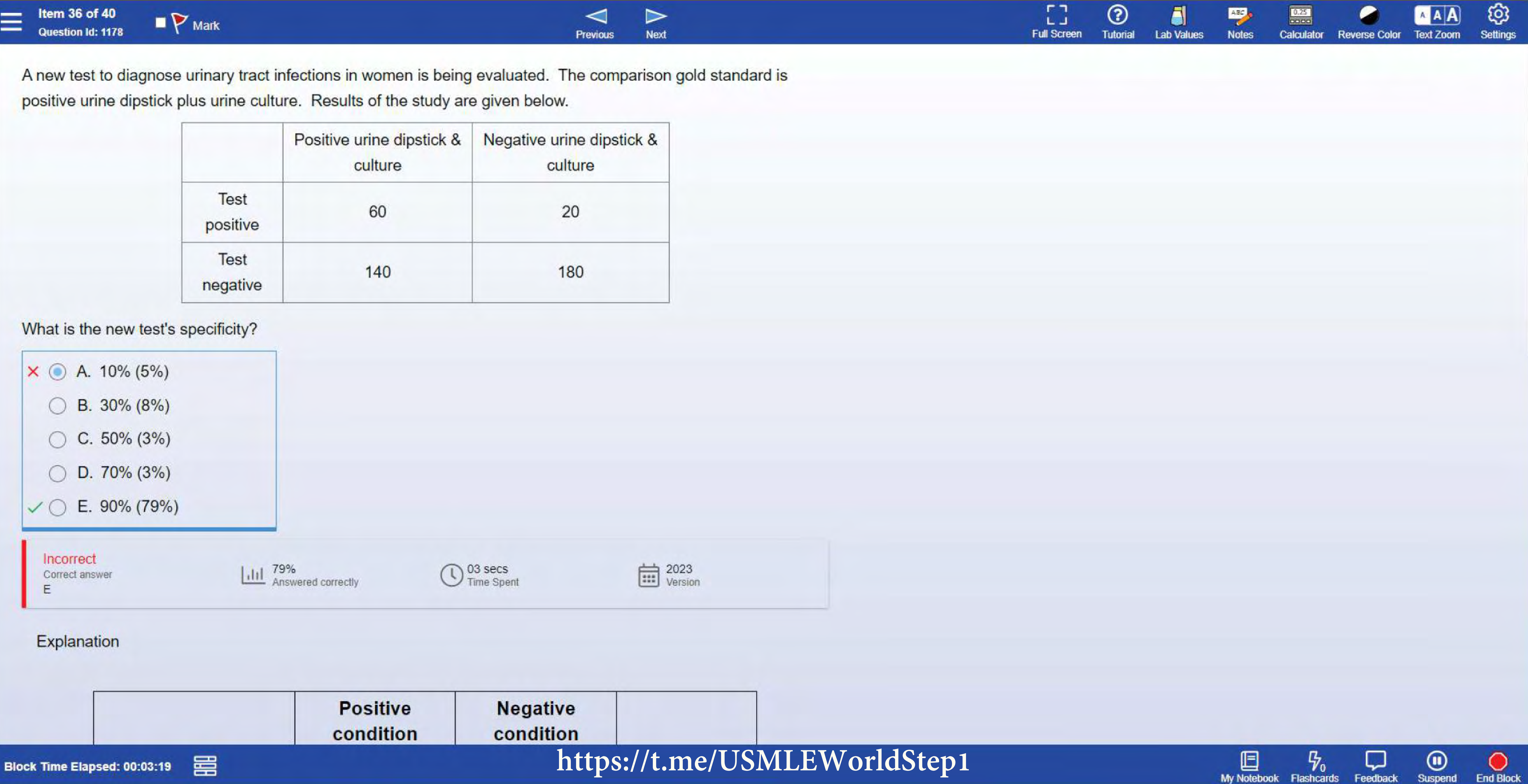
A new test to diagnose urinary tract infections in women is being evaluated. The comparison gold standard is positive urine dipstick plus urine culture. Results of the study are given below.

	Positive urine dipstick & culture	Negative urine dipstick & culture
Test positive	60	20
Test negative	140	180

What is the new test's specificity?

○ A. 10%
○ B. 30%
○ C. 50%
○ D. 70%
○ E. 90%

Submit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A new test to diagnose urinary tract infections in women is being evaluated. The comparison gold standard is positive urine dipstick plus urine culture. Results of the study are given below.

	Positive urine dipstick & culture	Negative urine dipstick & culture
Test positive	60	20
Test negative	140	180

What is the new test's specificity?

- ✗ ● A. 10% (5%)
- ○ B. 30% (8%)
- ○ C. 50% (3%)
- ○ D. 70% (3%)
- ✓ ○ E. 90% (79%)

Incorrect
Correct answer
E

79%
Answered correctly

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Explanation

	Positive condition	Negative condition	

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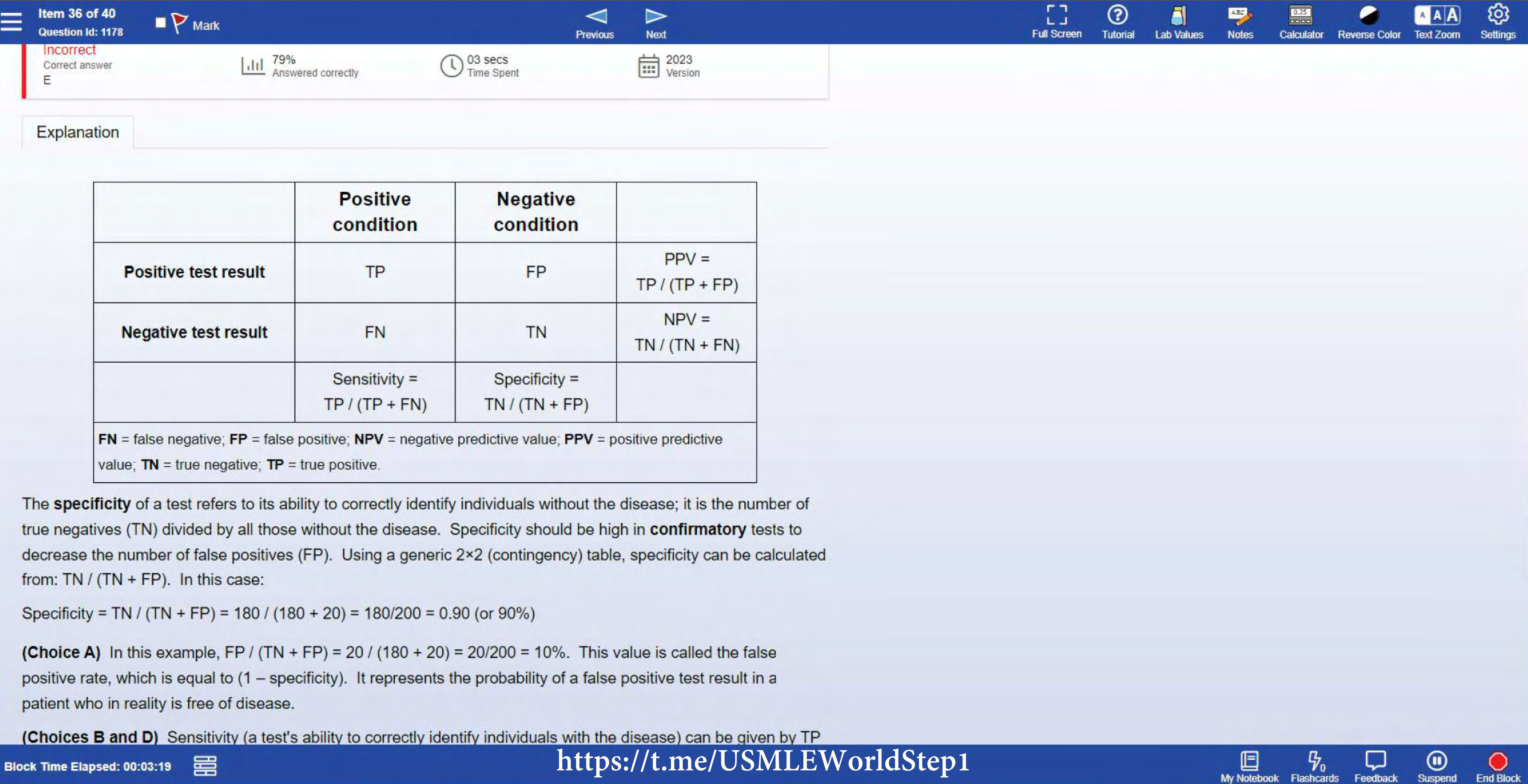
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Incorrect
Correct answer
E

79%
Answered correctly

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Explanation

	Positive condition	**Negative condition**	
Positive test result	TP	FP	PPV = TP / (TP + FP)
Negative test result	FN	TN	NPV = TN / (TN + FN)
	Sensitivity = TP / (TP + FN)	Specificity = TN / (TN + FP)	

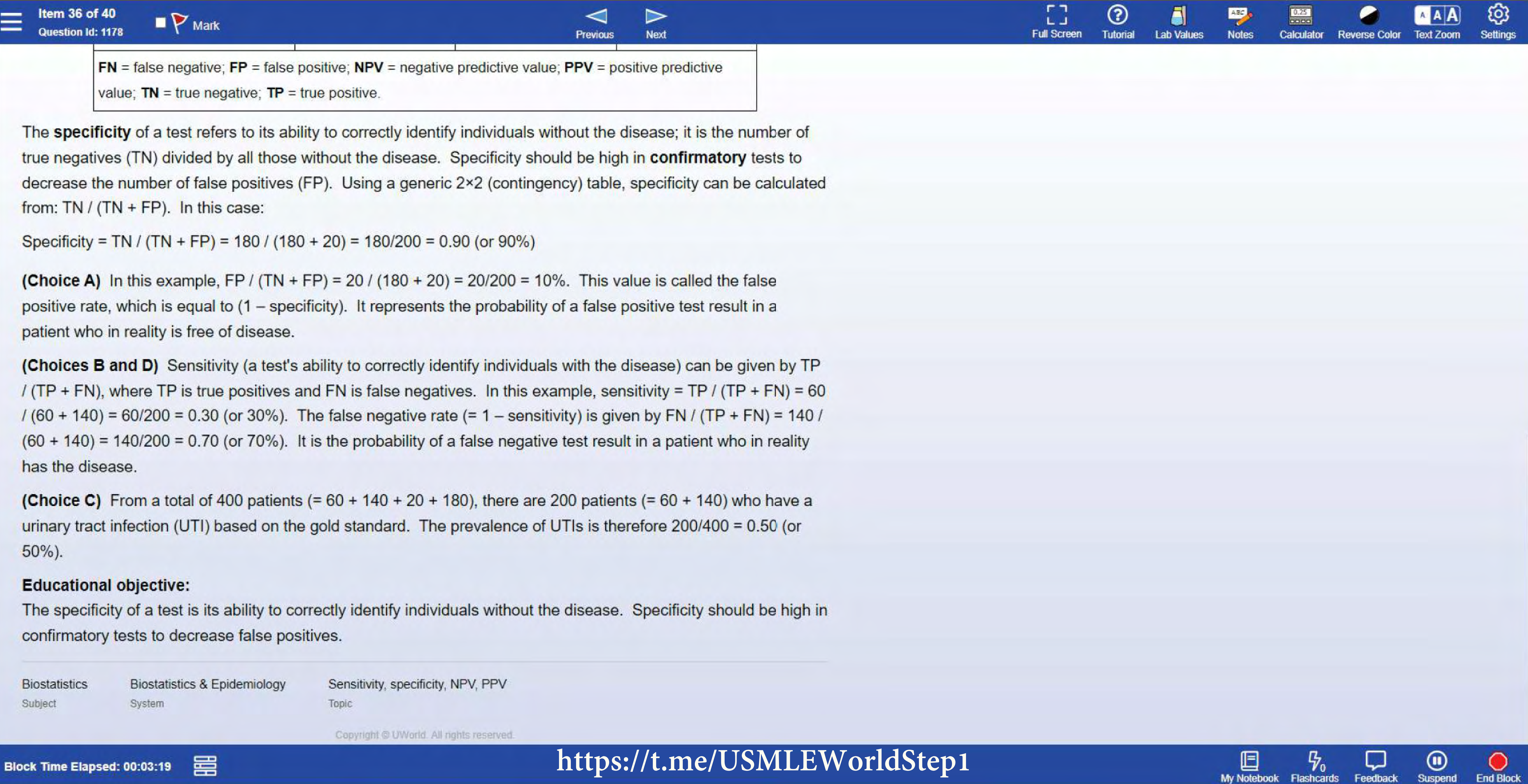
FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

The **specificity** of a test refers to its ability to correctly identify individuals without the disease; it is the number of true negatives (TN) divided by all those without the disease. Specificity should be high in **confirmatory** tests to decrease the number of false positives (FP). Using a generic 2×2 (contingency) table, specificity can be calculated from: TN / (TN + FP). In this case:

Specificity = TN / (TN + FP) = 180 / (180 + 20) = 180/200 = 0.90 (or 90%)

(Choice A) In this example, FP / (TN + FP) = 20 / (180 + 20) = 20/200 = 10%. This value is called the false positive rate, which is equal to (1 – specificity). It represents the probability of a false positive test result in a patient who in reality is free of disease.

(Choices B and D) Sensitivity (a test's ability to correctly identify individuals with the disease) can be given by TP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FN = false negative; **FP** = false positive; **NPV** = negative predictive value; **PPV** = positive predictive value; **TN** = true negative; **TP** = true positive.

The **specificity** of a test refers to its ability to correctly identify individuals without the disease; it is the number of true negatives (TN) divided by all those without the disease. Specificity should be high in **confirmatory** tests to decrease the number of false positives (FP). Using a generic 2×2 (contingency) table, specificity can be calculated from: TN / (TN + FP). In this case:

Specificity = TN / (TN + FP) = 180 / (180 + 20) = 180/200 = 0.90 (or 90%)

(Choice A) In this example, FP / (TN + FP) = 20 / (180 + 20) = 20/200 = 10%. This value is called the false positive rate, which is equal to (1 – specificity). It represents the probability of a false positive test result in a patient who in reality is free of disease.

(Choices B and D) Sensitivity (a test's ability to correctly identify individuals with the disease) can be given by TP / (TP + FN), where TP is true positives and FN is false negatives. In this example, sensitivity = TP / (TP + FN) = 60 / (60 + 140) = 60/200 = 0.30 (or 30%). The false negative rate (= 1 – sensitivity) is given by FN / (TP + FN) = 140 / (60 + 140) = 140/200 = 0.70 (or 70%). It is the probability of a false negative test result in a patient who in reality has the disease.

(Choice C) From a total of 400 patients (= 60 + 140 + 20 + 180), there are 200 patients (= 60 + 140) who have a urinary tract infection (UTI) based on the gold standard. The prevalence of UTIs is therefore 200/400 = 0.50 (or 50%).

Educational objective:
The specificity of a test is its ability to correctly identify individuals without the disease. Specificity should be high in confirmatory tests to decrease false positives.

Biostatistics	Biostatistics & Epidemiology	Sensitivity, specificity, NPV, PPV
Subject	System	Topic

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A large, multi-country study is conducted to determine the effect of economic development on cancer incidence and mortality. The study uses data obtained from the national cancer registries, along with information regarding per capita gross domestic product as reported by the International Monetary Fund and life expectancy as reported by the World Health Organization. Which of the following best describes the design of this study?

○ A. Case-control study
○ B. Cohort study
○ C. Cross-sectional survey
○ D. Ecological study
○ E. Nested case-control study
○ F. Qualitative study
○ G. Randomized controlled trial
○ H. Systematic review

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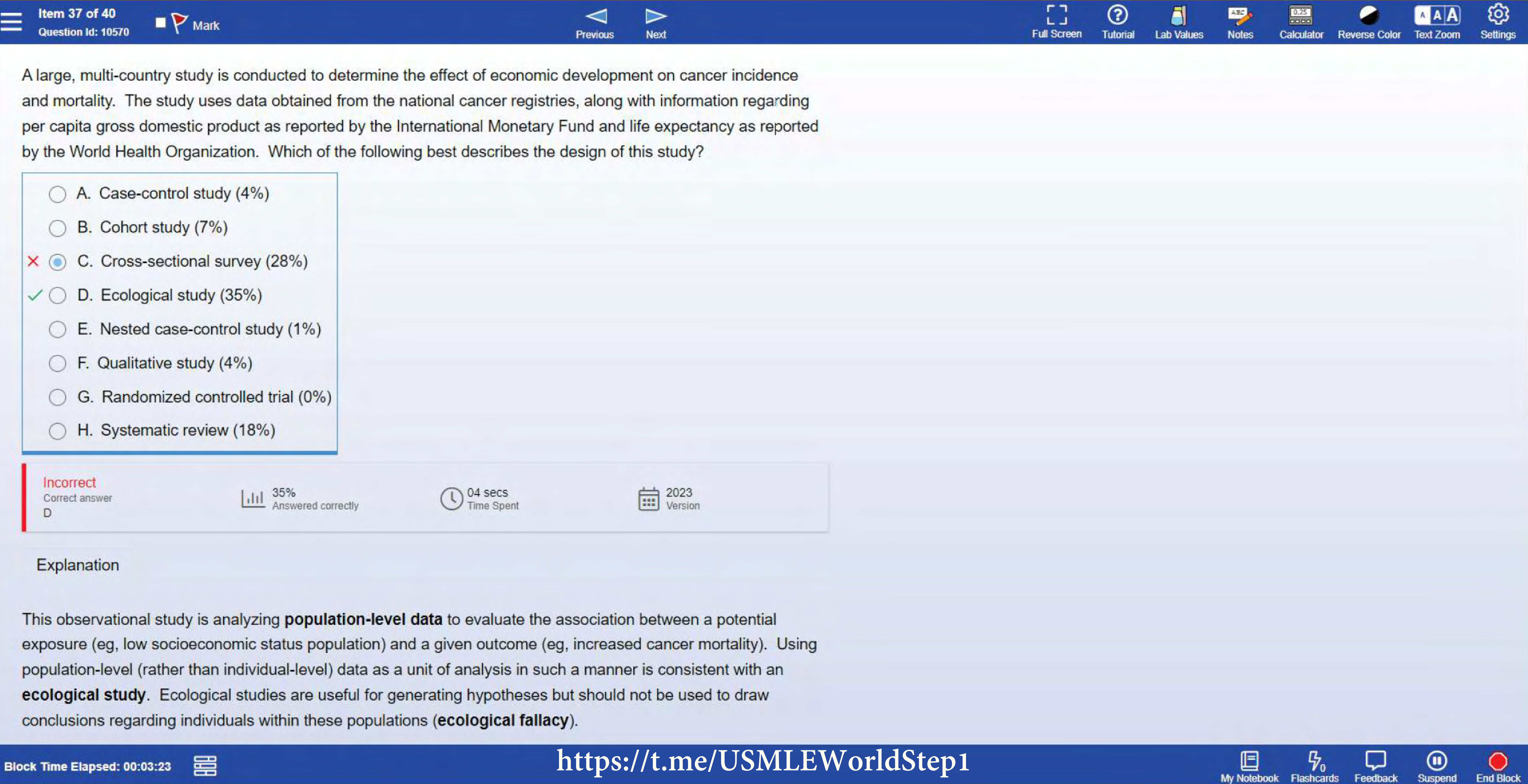
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A large, multi-country study is conducted to determine the effect of economic development on cancer incidence and mortality. The study uses data obtained from the national cancer registries, along with information regarding per capita gross domestic product as reported by the International Monetary Fund and life expectancy as reported by the World Health Organization. Which of the following best describes the design of this study?

○ A. Case-control study (4%)
○ B. Cohort study (7%)
✗ ● C. Cross-sectional survey (28%)
✓ ○ D. Ecological study (35%)
○ E. Nested case-control study (1%)
○ F. Qualitative study (4%)
○ G. Randomized controlled trial (0%)
○ H. Systematic review (18%)

Incorrect
Correct answer
D

35%
Answered correctly

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Explanation

This observational study is analyzing **population-level data** to evaluate the association between a potential exposure (eg, low socioeconomic status population) and a given outcome (eg, increased cancer mortality). Using population-level (rather than individual-level) data as a unit of analysis in such a manner is consistent with an **ecological study**. Ecological studies are useful for generating hypotheses but should not be used to draw conclusions regarding individuals within these populations (**ecological fallacy**).

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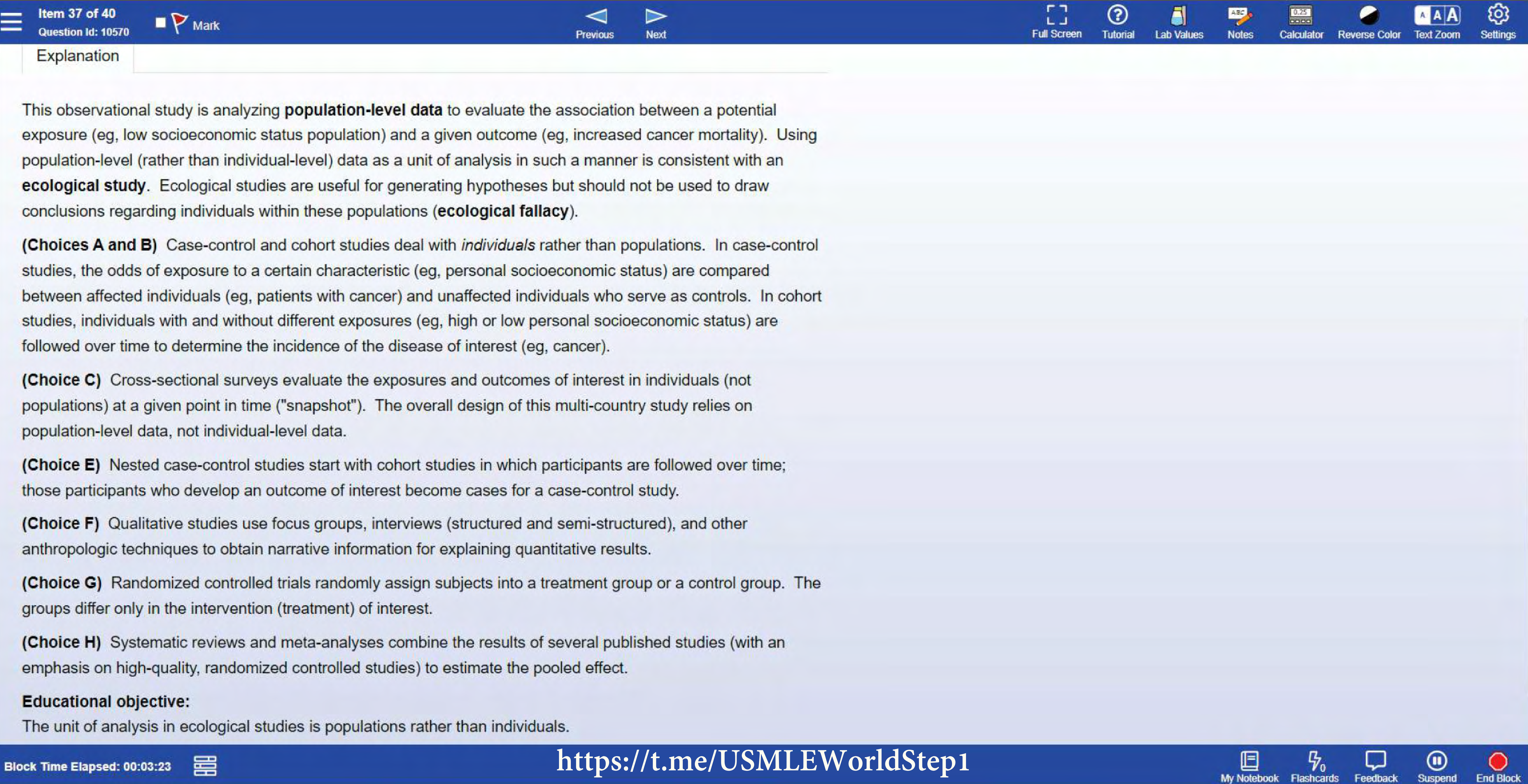


This observational study is analyzing **population-level data** to evaluate the association between a potential exposure (eg, low socioeconomic status population) and a given outcome (eg, increased cancer mortality). Using population-level (rather than individual-level) data as a unit of analysis in such a manner is consistent with an **ecological study**. Ecological studies are useful for generating hypotheses but should not be used to draw conclusions regarding individuals within these populations (**ecological fallacy**).

(Choices A and B) Case-control and cohort studies deal with *individuals* rather than populations. In case-control studies, the odds of exposure to a certain characteristic (eg, personal socioeconomic status) are compared between affected individuals (eg, patients with cancer) and unaffected individuals who serve as controls. In cohort studies, individuals with and without different exposures (eg, high or low personal socioeconomic status) are followed over time to determine the incidence of the disease of interest (eg, cancer).

(Choice C) Cross-sectional surveys evaluate the exposures and outcomes of interest in individuals (not populations) at a given point in time ("snapshot"). The overall design of this multi-country study relies on population-level data, not individual-level data.

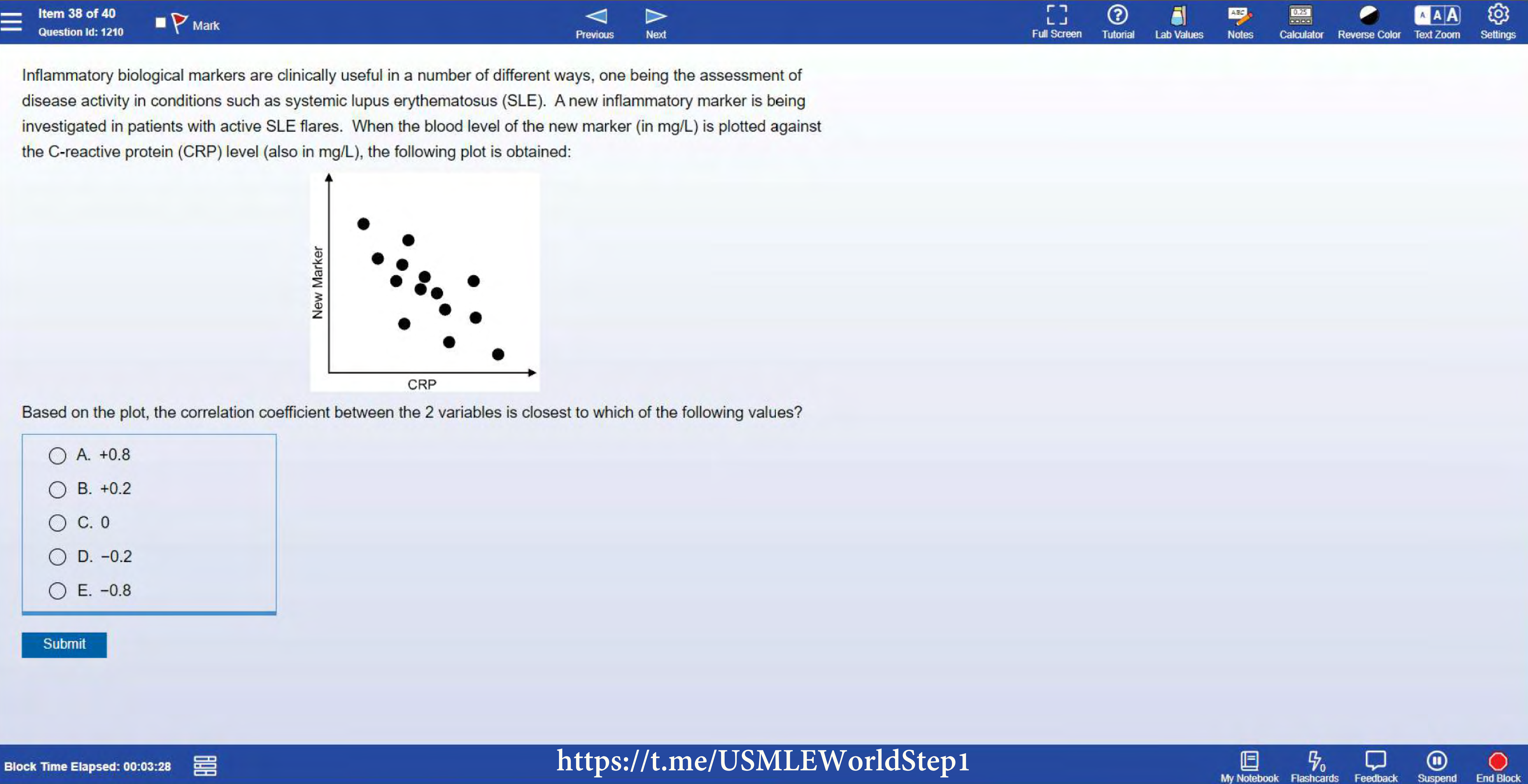
(Choice E) Nested case-control studies start with cohort studies in which participants are followed over time; those participants who develop an outcome of interest become cases for a case-control study.

(Choice F) Qualitative studies use focus groups, interviews (structured and semi-structured), and other anthropologic techniques to obtain narrative information for explaining quantitative results.

(Choice G) Randomized controlled trials randomly assign subjects into a treatment group or a control group. The groups differ only in the intervention (treatment) of interest.

(Choice H) Systematic reviews and meta-analyses combine the results of several published studies (with an emphasis on high-quality, randomized controlled studies) to estimate the pooled effect.

Educational objective:
The unit of analysis in ecological studies is populations rather than individuals.



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Inflammatory biological markers are clinically useful in a number of different ways, one being the assessment of disease activity in conditions such as systemic lupus erythematosus (SLE). A new inflammatory marker is being investigated in patients with active SLE flares. When the blood level of the new marker (in mg/L) is plotted against the C-reactive protein (CRP) level (also in mg/L), the following plot is obtained:

New Marker
CRP

Based on the plot, the correlation coefficient between the 2 variables is closest to which of the following values?

○ A. +0.8
○ B. +0.2
○ C. 0
○ D. −0.2
○ E. −0.8

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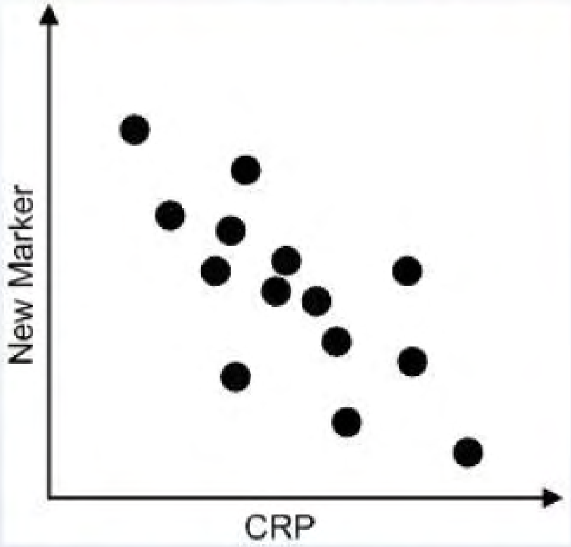
Inflammatory biological markers are clinically useful in a number of different ways, one being the assessment of disease activity in conditions such as systemic lupus erythematosus (SLE). A new inflammatory marker is being investigated in patients with active SLE flares. When the blood level of the new marker (in mg/L) is plotted against the C-reactive protein (CRP) level (also in mg/L), the following plot is obtained:



Based on the plot, the correlation coefficient between the 2 variables is closest to which of the following values?

○ A. +0.8 (4%)
✕ ● B. +0.2 (5%)
○ C. 0 (6%)
○ D. −0.2 (10%)
✓ ○ E. −0.8 (73%)

Incorrect
Correct answer
E

73%
Answered correctly

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Explanation

Explanation

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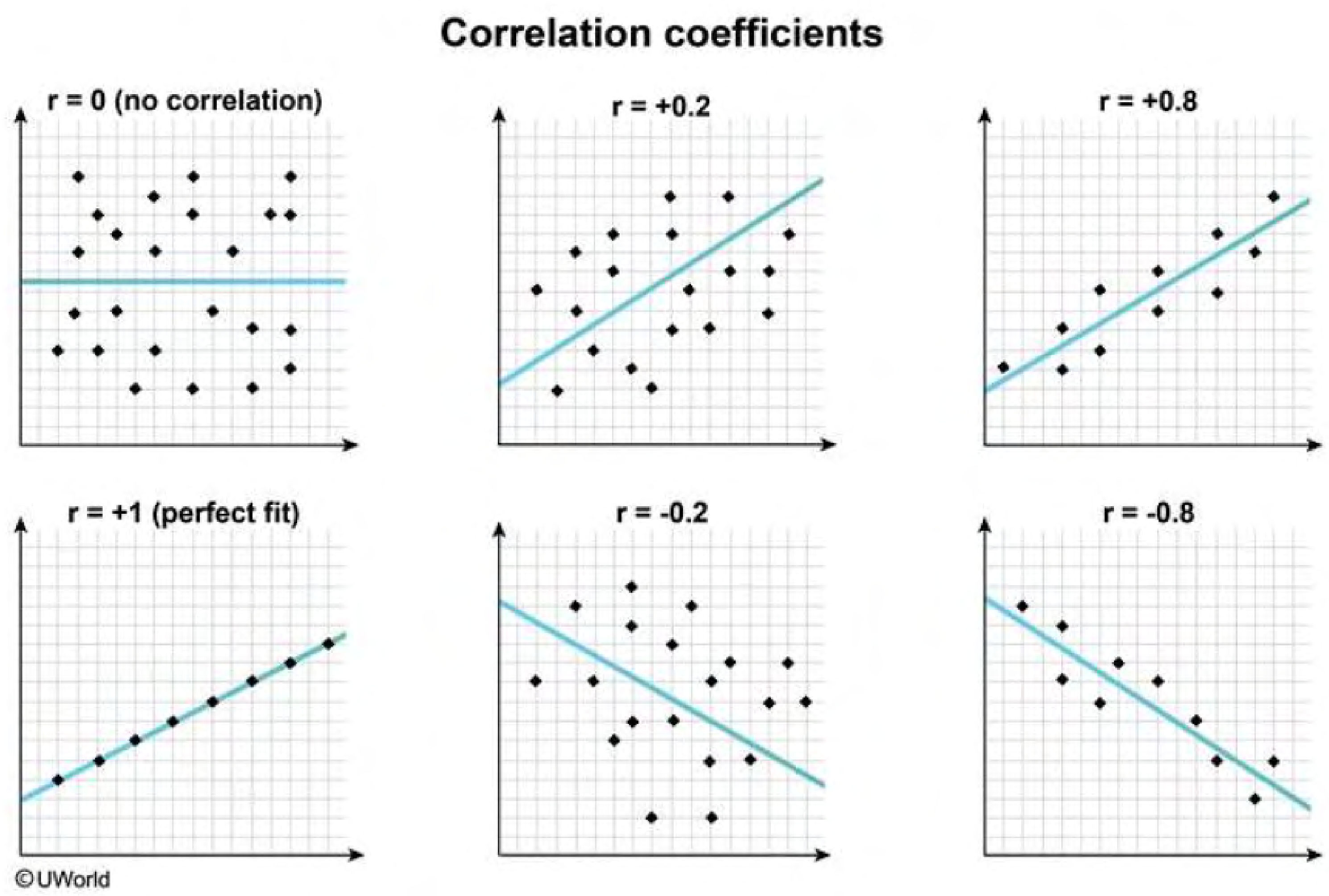

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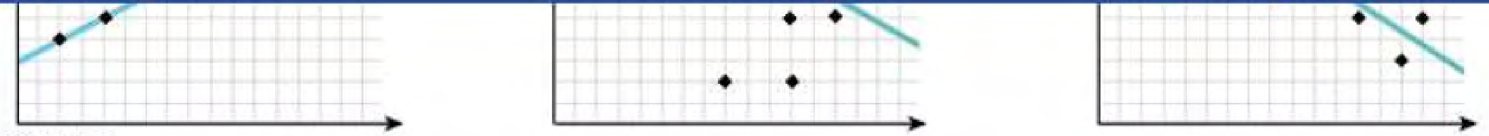
linear
Therefore, the most appropriate answer among the options given is r = −0.8.



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Scatter plots are useful for crude data analysis. If a **linear** association is present between 2 variables, a **correlation coefficient** (r) mathematically describes how well a "line of best fit" (blue line in Figure) would correspond to the data points plotted. The value of r ranges from **−1 to +1** and describes 2 important characteristics of an association: the strength and the polarity. The closer the r value is to its margins [−1, 1], the stronger the association.

An increase in C-reactive protein (CRP) level is associated with a decrease in the new marker's level; therefore, r <0. Although the scatter plot does not demonstrate a perfect linear arrangement, it does show a reasonably strong linear association as there is minimal variation along the line of best fit (points are relatively close to the line). Therefore, the most appropriate answer among the options given is r = −0.8.

(Choices A and B) In this example, r cannot be >0 as an increase in CRP level is associated with a decrease in the new marker's level.

(Choice C) An r = 0 indicates that there is no association (ie, a random distribution).

(Choice D) An r = −0.2 would also indicate a negative association; however, there would be more variation along the line of best fit (as seen in the Figure).

The value of r is **not** the slope of the line of best fit. For instance, assuming a data set with a maximum positive association (ie, all data points forming a straight line with a positive slope), the line of best fit will always have r = +1, even if its actual slope is 0.2, 5.5, or any other positive value (as seen in the Figure).

Educational objective:

The correlation coefficient (r) ranges from −1 to +1 and describes the strength and polarity of a linear association.

Biostatistics	Biostatistics & Epidemiology	Correlation coefficient
Subject	System	Topic

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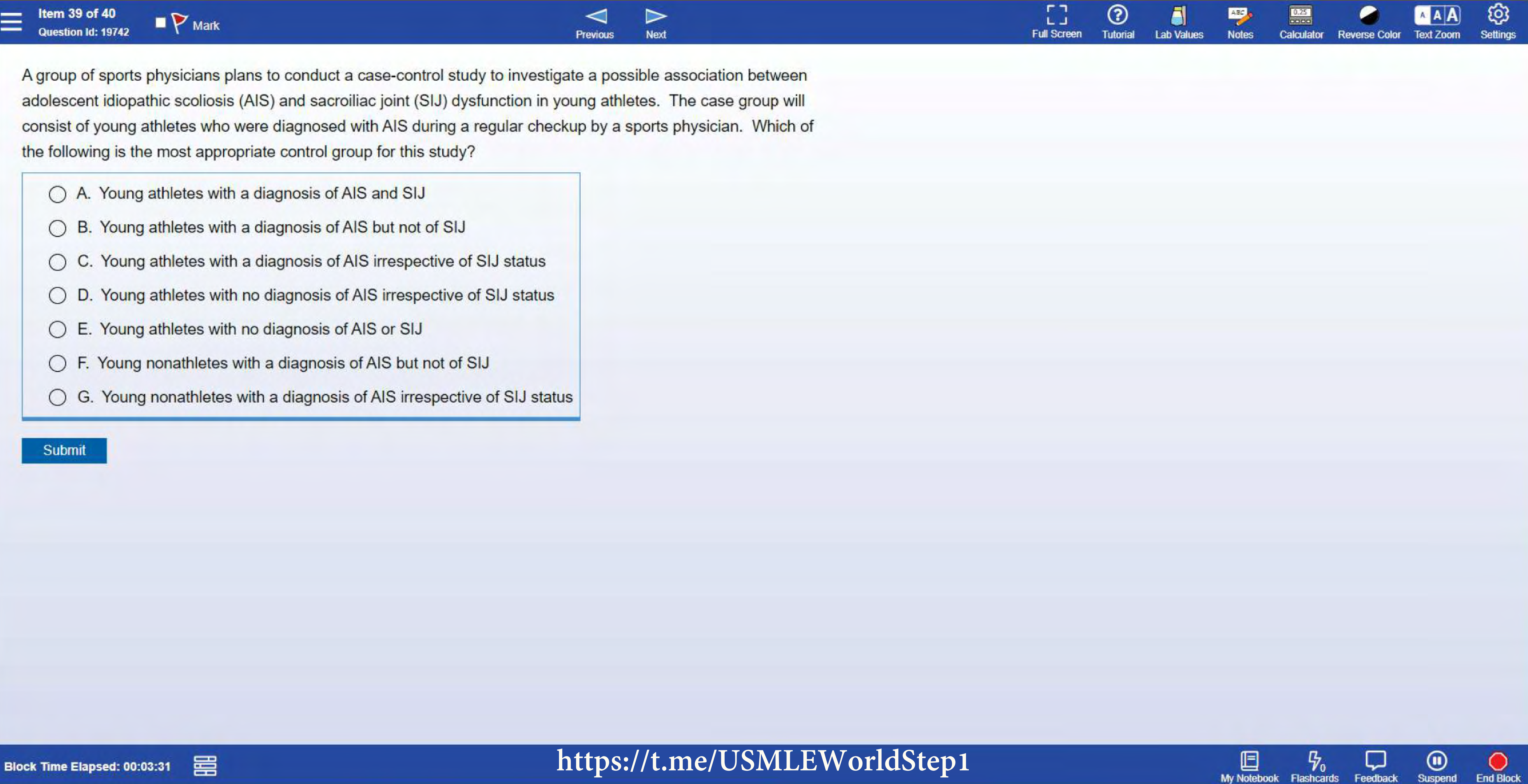
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A group of sports physicians plans to conduct a case-control study to investigate a possible association between adolescent idiopathic scoliosis (AIS) and sacroiliac joint (SIJ) dysfunction in young athletes. The case group will consist of young athletes who were diagnosed with AIS during a regular checkup by a sports physician. Which of the following is the most appropriate control group for this study?

○ A. Young athletes with a diagnosis of AIS and SIJ

○ B. Young athletes with a diagnosis of AIS but not of SIJ

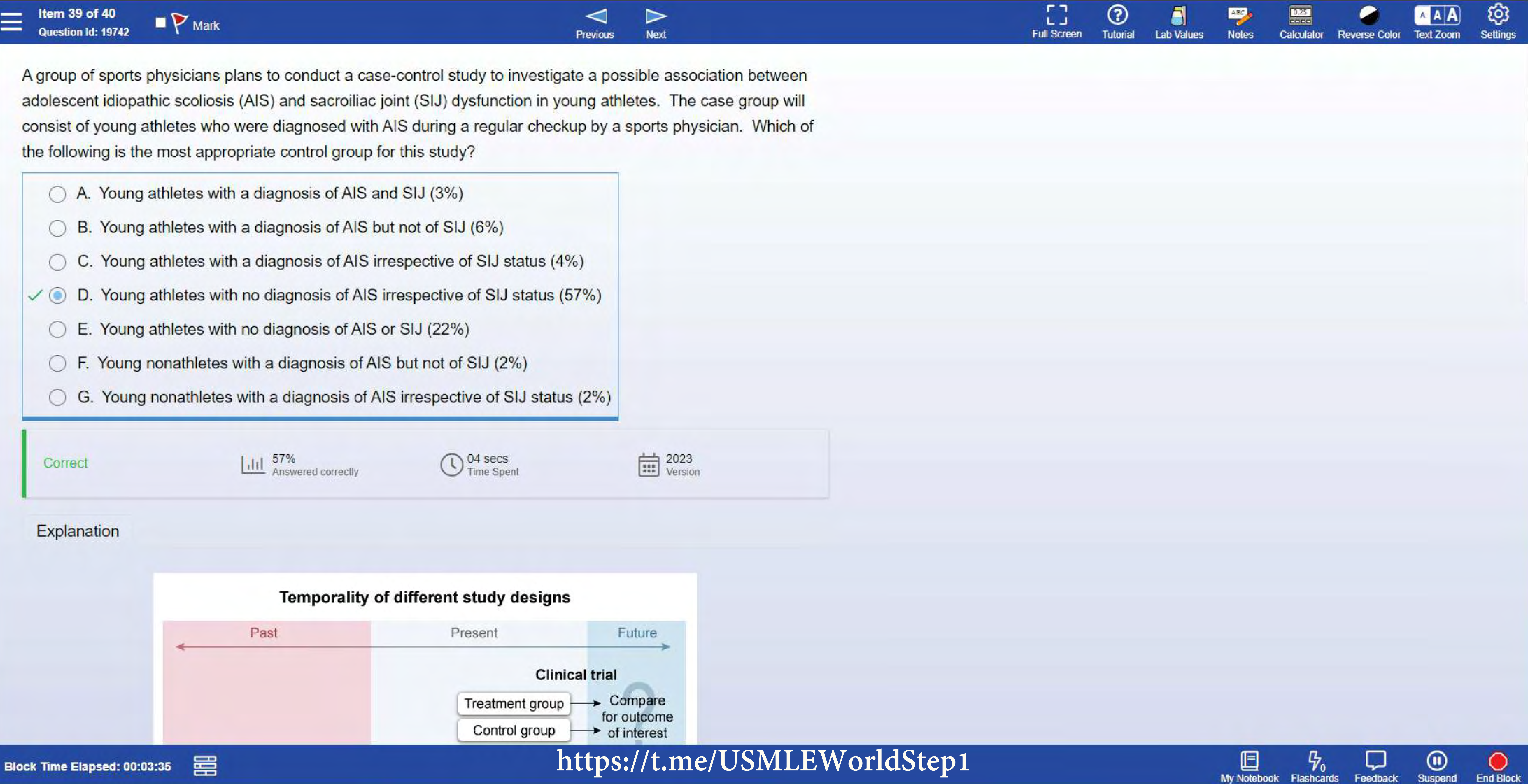
○ C. Young athletes with a diagnosis of AIS irrespective of SIJ status

○ D. Young athletes with no diagnosis of AIS irrespective of SIJ status

○ E. Young athletes with no diagnosis of AIS or SIJ

○ F. Young nonathletes with a diagnosis of AIS but not of SIJ

○ G. Young nonathletes with a diagnosis of AIS irrespective of SIJ status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○ A. Young athletes with a diagnosis of AIS and SIJ (3%)
○ B. Young athletes with a diagnosis of AIS but not of SIJ (6%)
○ C. Young athletes with a diagnosis of AIS irrespective of SIJ status (4%)
✓ ● D. Young athletes with no diagnosis of AIS irrespective of SIJ status (57%)
○ E. Young athletes with no diagnosis of AIS or SIJ (22%)
○ F. Young nonathletes with a diagnosis of AIS but not of SIJ (2%)
○ G. Young nonathletes with a diagnosis of AIS irrespective of SIJ status (2%)

Correct
57% Answered correctly
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Explanation

Temporality of different study designs

Past
Present
Future
Clinical trial
Treatment group
Control group
Compare for outcome of interest

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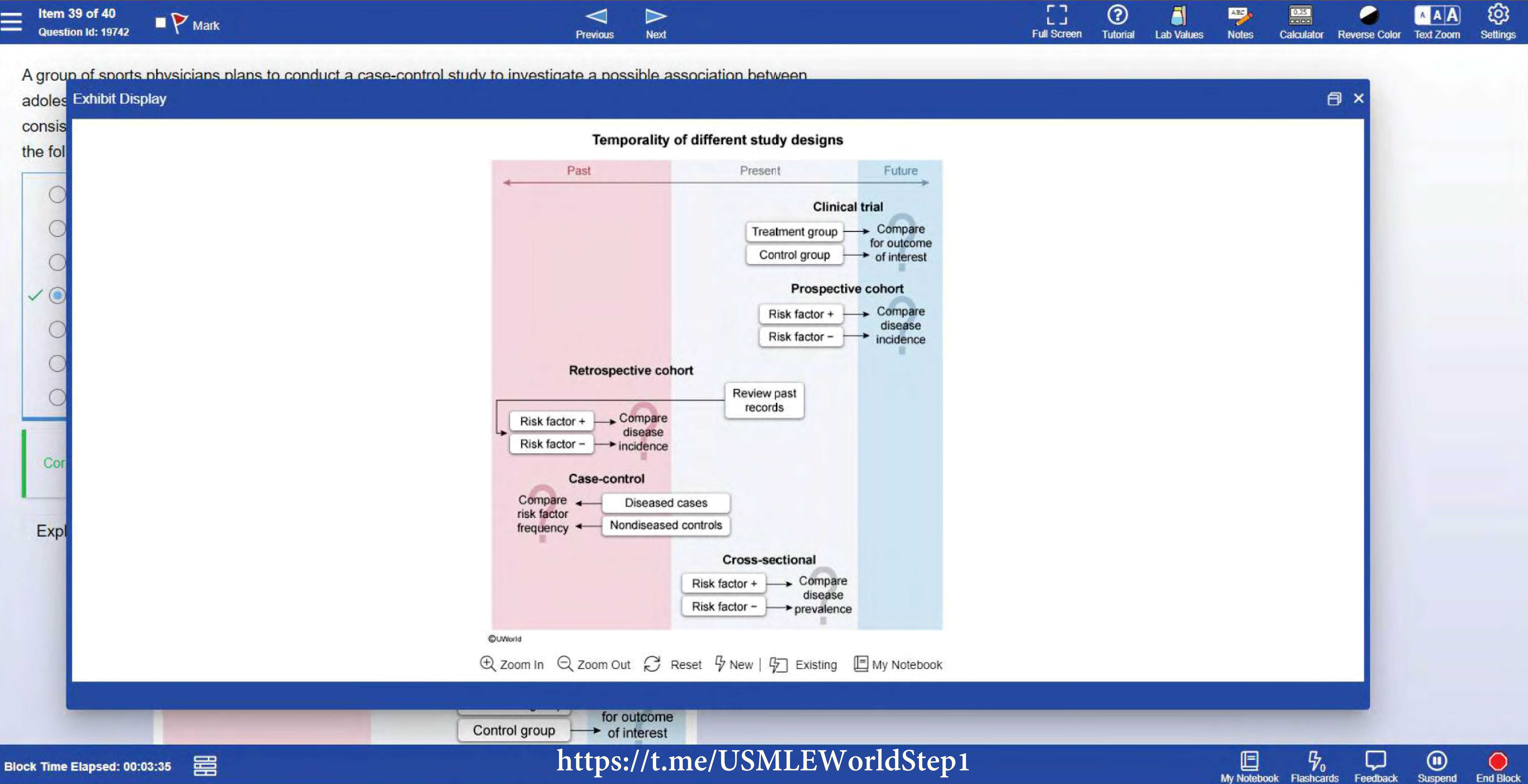
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Temporality of different study designs

Past
Present
Future
Clinical trial
Treatment group
Control group
Compare for outcome of interest
Prospective cohort
Risk factor +
Risk factor –
Compare disease incidence
Retrospective cohort
Review past records
Risk factor +
Risk factor –
Compare disease incidence
Case-control
Compare risk factor frequency
Diseased cases
Nondiseased controls
Cross-sectional
Risk factor +
Risk factor –
Compare disease prevalence
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Control group
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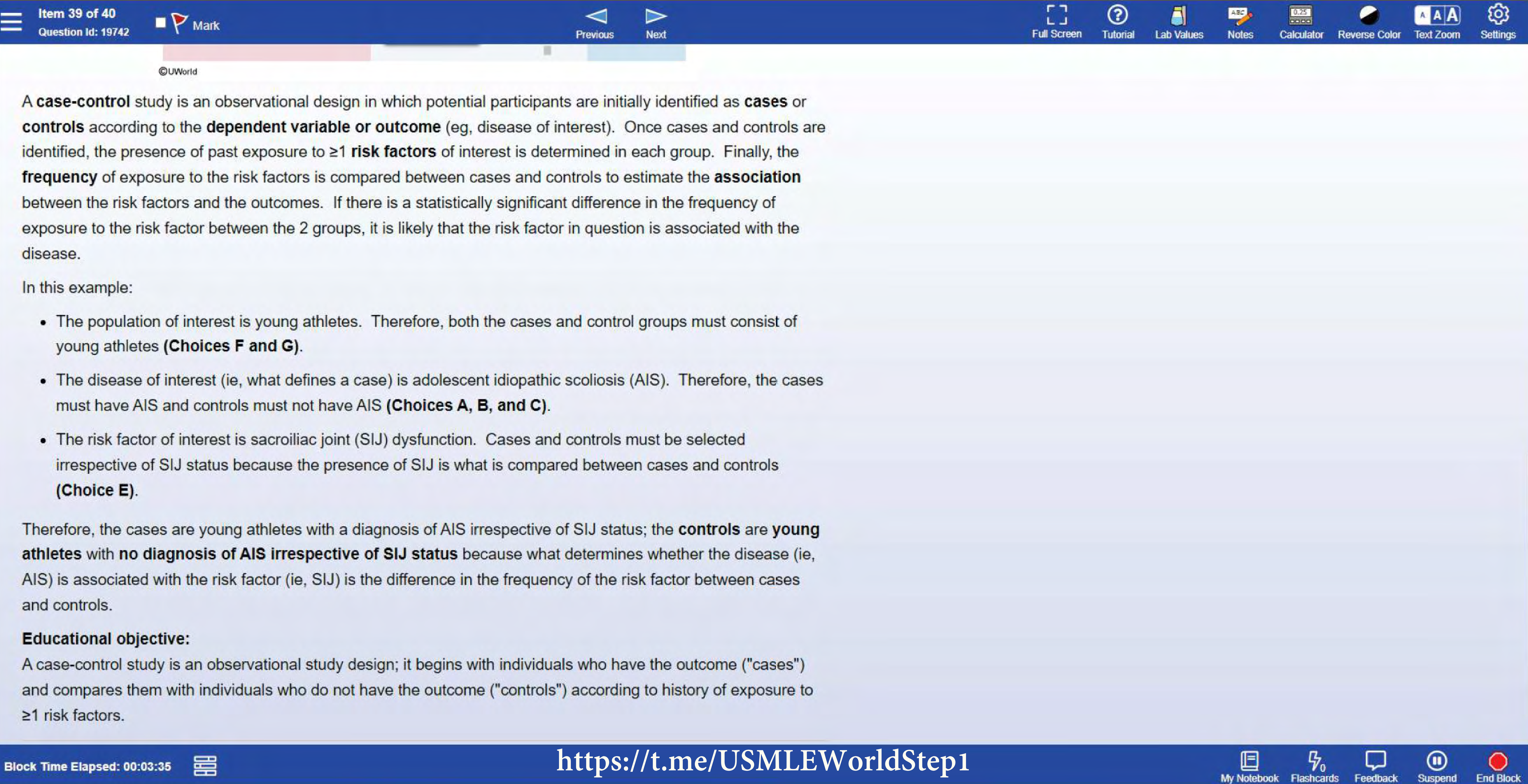
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A **case-control** study is an observational design in which potential participants are initially identified as **cases** or **controls** according to the **dependent variable or outcome** (eg, disease of interest). Once cases and controls are identified, the presence of past exposure to ≥1 **risk factors** of interest is determined in each group. Finally, the **frequency** of exposure to the risk factors is compared between cases and controls to estimate the **association** between the risk factors and the outcomes. If there is a statistically significant difference in the frequency of exposure to the risk factor between the 2 groups, it is likely that the risk factor in question is associated with the disease.

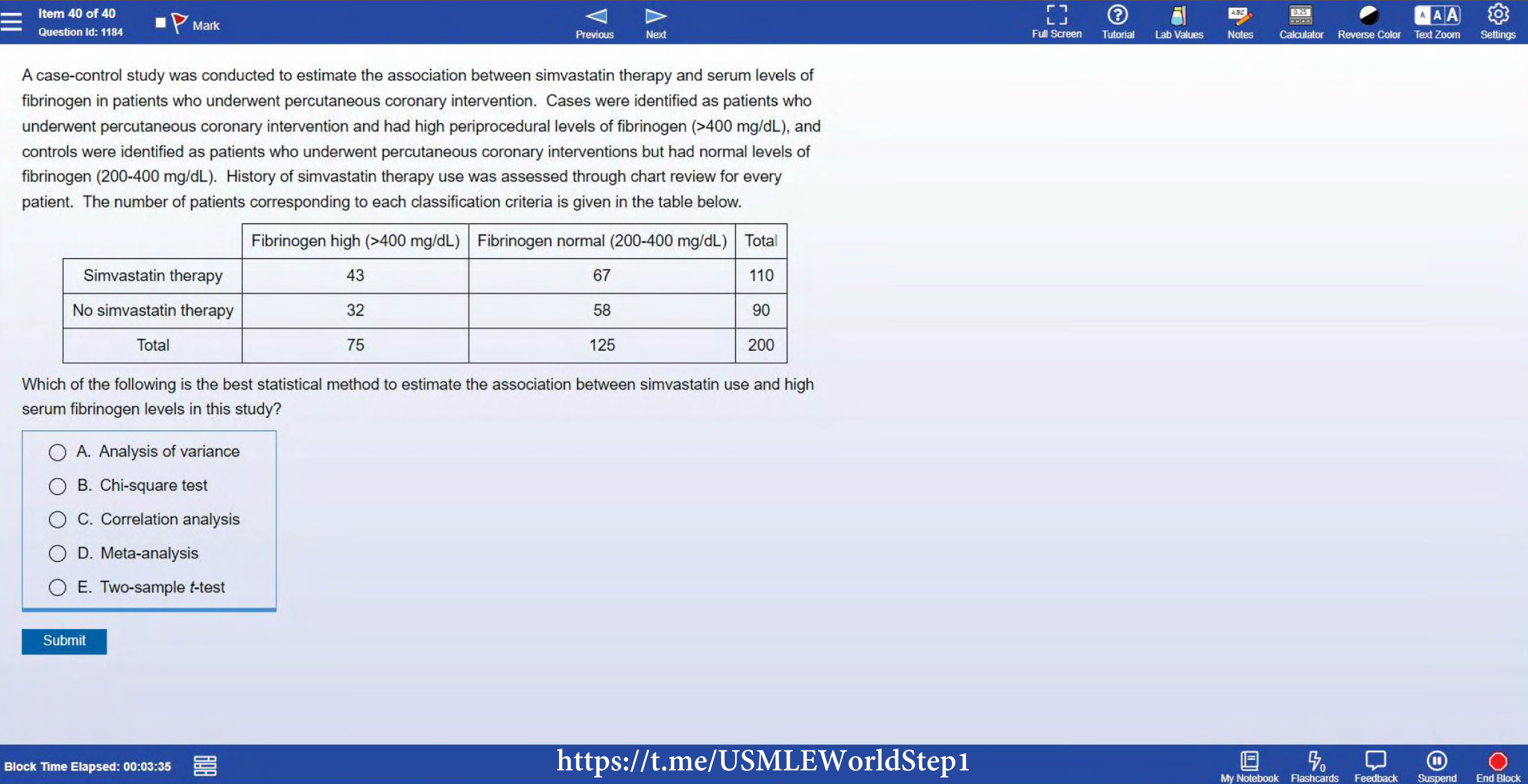
In this example:

- The population of interest is young athletes. Therefore, both the cases and control groups must consist of young athletes **(Choices F and G)**.
- The disease of interest (ie, what defines a case) is adolescent idiopathic scoliosis (AIS). Therefore, the cases must have AIS and controls must not have AIS **(Choices A, B, and C)**.
- The risk factor of interest is sacroiliac joint (SIJ) dysfunction. Cases and controls must be selected irrespective of SIJ status because the presence of SIJ is what is compared between cases and controls **(Choice E)**.

Therefore, the cases are young athletes with a diagnosis of AIS irrespective of SIJ status; the **controls** are **young athletes** with **no diagnosis of AIS irrespective of SIJ status** because what determines whether the disease (ie, AIS) is associated with the risk factor (ie, SIJ) is the difference in the frequency of the risk factor between cases and controls.

Educational objective:

A case-control study is an observational study design; it begins with individuals who have the outcome ("cases") and compares them with individuals who do not have the outcome ("controls") according to history of exposure to ≥1 risk factors.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A case-control study was conducted to estimate the association between simvastatin therapy and serum levels of fibrinogen in patients who underwent percutaneous coronary intervention. Cases were identified as patients who underwent percutaneous coronary intervention and had high periprocedural levels of fibrinogen (>400 mg/dL), and controls were identified as patients who underwent percutaneous coronary interventions but had normal levels of fibrinogen (200-400 mg/dL). History of simvastatin therapy use was assessed through chart review for every patient. The number of patients corresponding to each classification criteria is given in the table below.

	Fibrinogen high (>400 mg/dL)	Fibrinogen normal (200-400 mg/dL)	Total
Simvastatin therapy	43	67	110
No simvastatin therapy	32	58	90
Total	75	125	200

Which of the following is the best statistical method to estimate the association between simvastatin use and high serum fibrinogen levels in this study?

○ A. Analysis of variance
○ B. Chi-square test
○ C. Correlation analysis
○ D. Meta-analysis
○ E. Two-sample *t*-test

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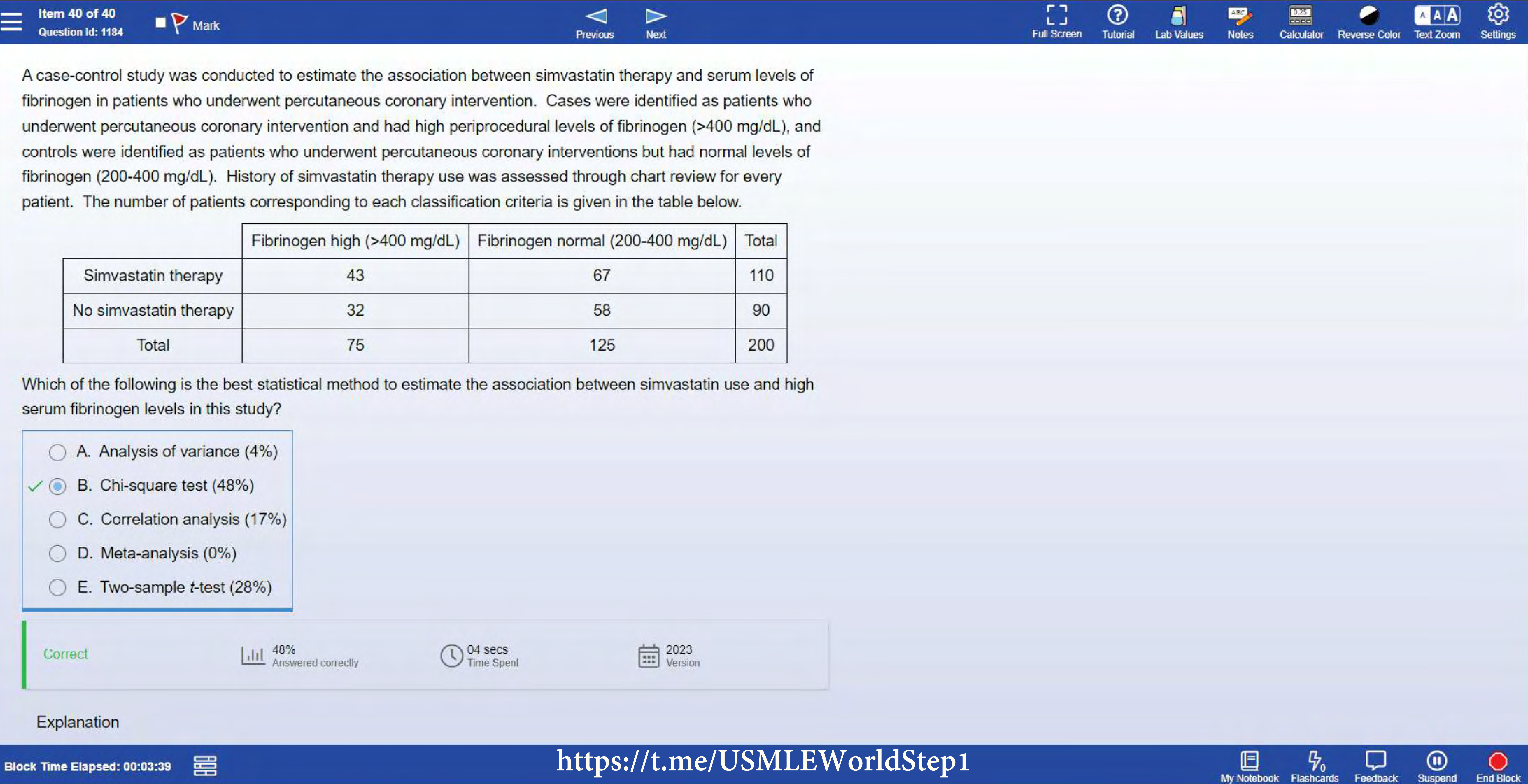
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Simvastatin therapy	43	67	110
No simvastatin therapy	32	58	90
Total	75	125	200

Which of the following is the best statistical method to estimate the association between simvastatin use and high serum fibrinogen levels in this study?

- ○ A. Analysis of variance (4%)
- ✓ ● B. Chi-square test (48%)
- ○ C. Correlation analysis (17%)
- ○ D. Meta-analysis (0%)
- ○ E. Two-sample *t*-test (28%)

Correct

48%
Answered correctly

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Explanation

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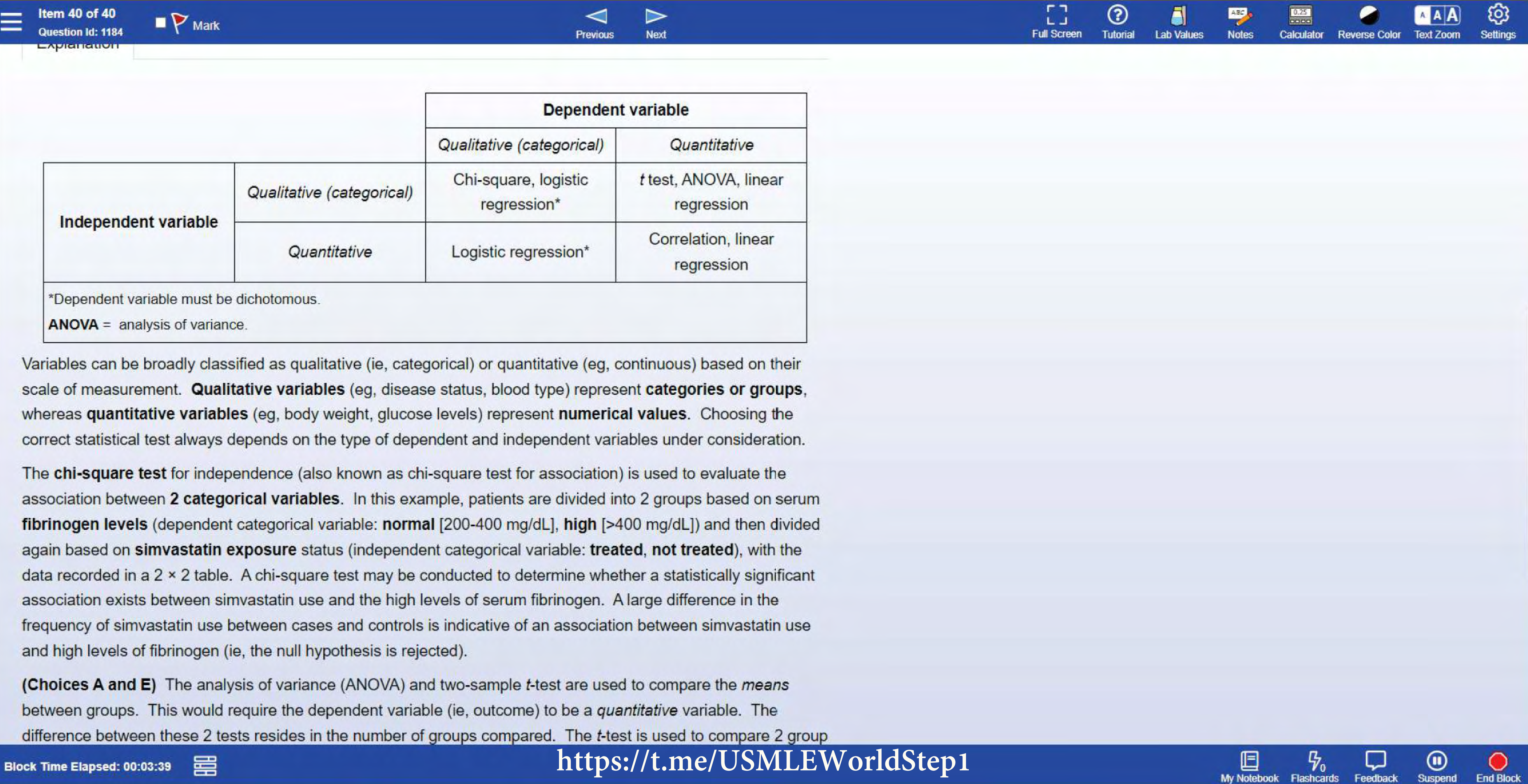
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		Dependent variable	
		Qualitative (categorical)	*Quantitative*
Independent variable	*Qualitative (categorical)*	Chi-square, logistic regression*	*t* test, ANOVA, linear regression
	Quantitative	Logistic regression*	Correlation, linear regression

*Dependent variable must be dichotomous.

ANOVA = analysis of variance.

Variables can be broadly classified as qualitative (ie, categorical) or quantitative (eg, continuous) based on their scale of measurement. **Qualitative variables** (eg, disease status, blood type) represent **categories or groups**, whereas **quantitative variables** (eg, body weight, glucose levels) represent **numerical values**. Choosing the correct statistical test always depends on the type of dependent and independent variables under consideration.

The **chi-square test** for independence (also known as chi-square test for association) is used to evaluate the association between **2 categorical variables**. In this example, patients are divided into 2 groups based on serum **fibrinogen levels** (dependent categorical variable: **normal** [200-400 mg/dL], **high** [>400 mg/dL]) and then divided again based on **simvastatin exposure** status (independent categorical variable: **treated**, **not treated**), with the data recorded in a 2 × 2 table. A chi-square test may be conducted to determine whether a statistically significant association exists between simvastatin use and the high levels of serum fibrinogen. A large difference in the frequency of simvastatin use between cases and controls is indicative of an association between simvastatin use and high levels of fibrinogen (ie, the null hypothesis is rejected).

(Choices A and E) The analysis of variance (ANOVA) and two-sample *t*-test are used to compare the *means* between groups. This would require the dependent variable (ie, outcome) to be a *quantitative* variable. The difference between these 2 tests resides in the number of groups compared. The *t*-test is used to compare 2 group

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scale of measurement. **Qualitative variables** (eg, disease status, blood type) represent **categories or groups**, whereas **quantitative variables** (eg, body weight, glucose levels) represent **numerical values**. Choosing the correct statistical test always depends on the type of dependent and independent variables under consideration.

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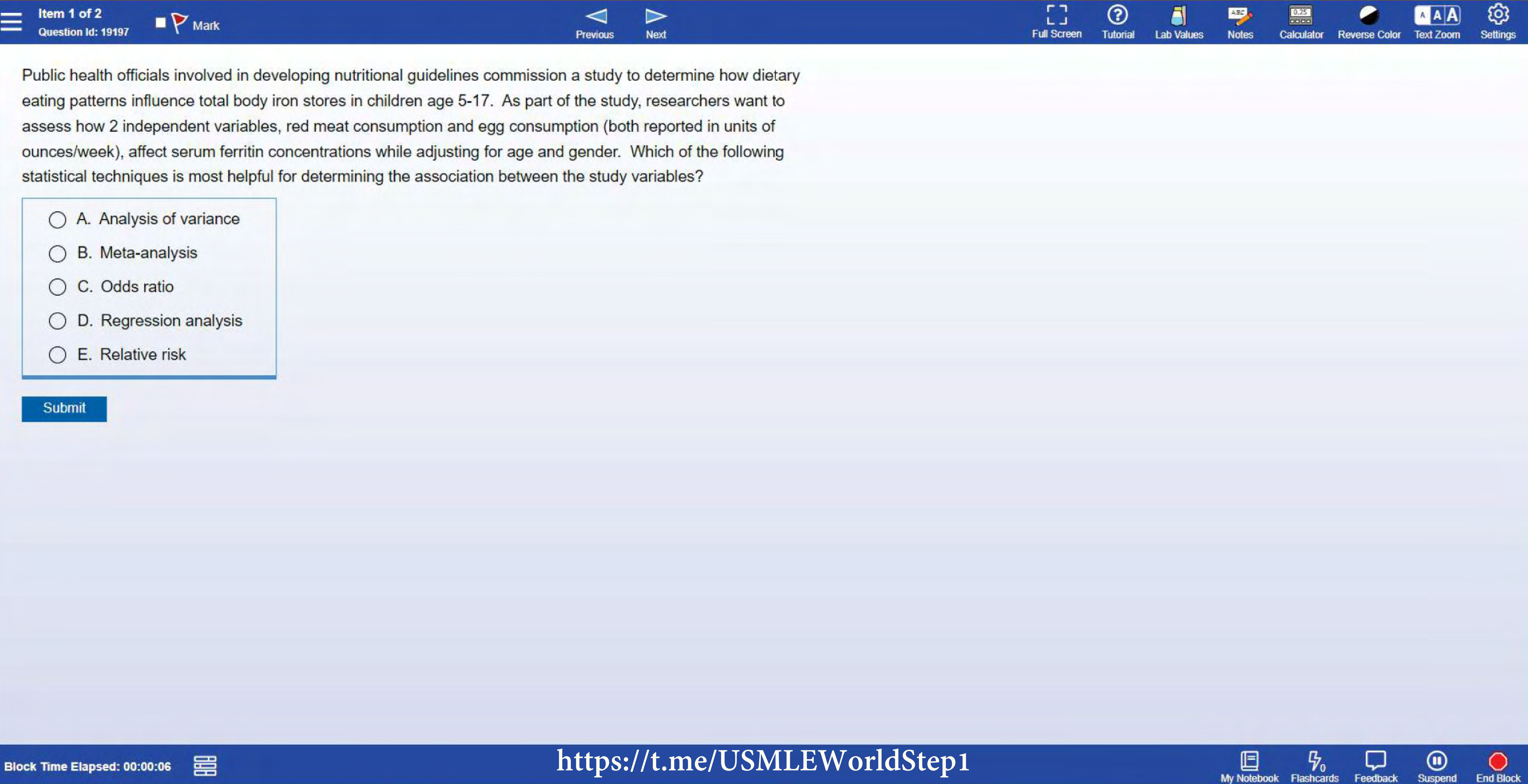
(Choices A and E) The analysis of variance (ANOVA) and two-sample *t*-test are used to compare the *means* between groups. This would require the dependent variable (ie, outcome) to be a *quantitative* variable. The difference between these 2 tests resides in the number of groups compared. The *t*-test is used to compare 2 group means, whereas the ANOVA is used to compare ≥2 group means. Either of these tests would be appropriate in this example if fibrinogen levels were recorded as a quantitative variable (ie, the actual measured level in mg/dL) instead of a categorical variable (ie, normal or high).

(Choice C) The correlation coefficient is a measure of the strength and direction of a linear relationship between 2 *quantitative* variables. For example, a study may report a correlation coefficient describing the association between hemoglobin A1c levels and average blood glucose levels.

(Choice D) Meta-analysis is an epidemiological method of pooling the data from several studies to conduct an analysis having a relatively larger statistical power than that of the individual studies.

Educational objective:

A 2 × 2 table is normally used to record the presence or absence of exposure and disease in research. Rows and columns represent the different levels for each categorical (ie, exposure and disease) variable. The chi-square test for independence is used to evaluate the association between 2 categorical variables.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Public health officials involved in developing nutritional guidelines commission a study to determine how dietary eating patterns influence total body iron stores in children age 5-17. As part of the study, researchers want to assess how 2 independent variables, red meat consumption and egg consumption (both reported in units of ounces/week), affect serum ferritin concentrations while adjusting for age and gender. Which of the following statistical techniques is most helpful for determining the association between the study variables?

○ A. Analysis of variance
○ B. Meta-analysis
○ C. Odds ratio
○ D. Regression analysis
○ E. Relative risk

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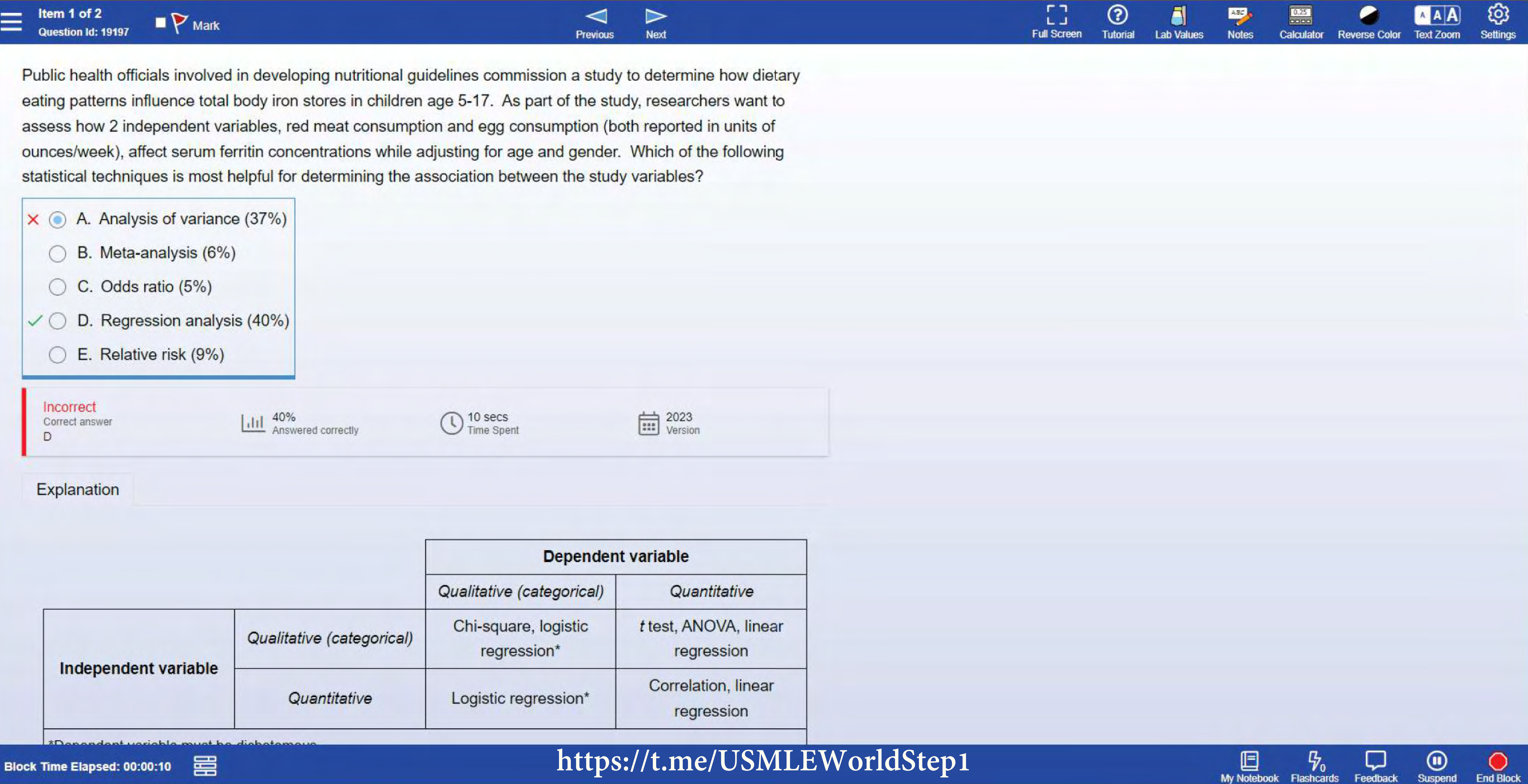
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Public health officials involved in developing nutritional guidelines commission a study to determine how dietary eating patterns influence total body iron stores in children age 5-17. As part of the study, researchers want to assess how 2 independent variables, red meat consumption and egg consumption (both reported in units of ounces/week), affect serum ferritin concentrations while adjusting for age and gender. Which of the following statistical techniques is most helpful for determining the association between the study variables?

✗ ● A. Analysis of variance (37%)
○ B. Meta-analysis (6%)
○ C. Odds ratio (5%)
✓ ○ D. Regression analysis (40%)
○ E. Relative risk (9%)

Incorrect
Correct answer
D

40%
Answered correctly

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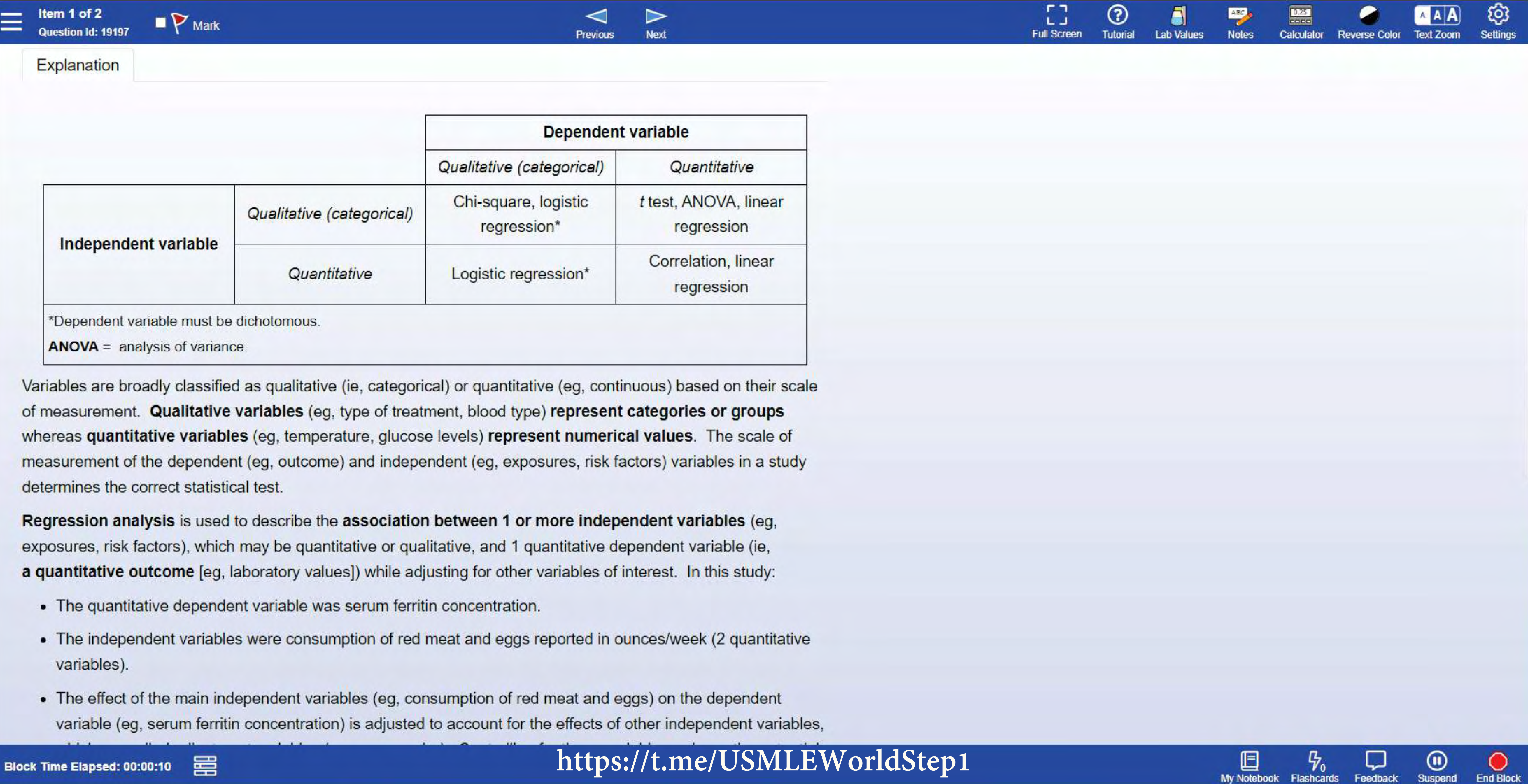
Explanation

		Dependent variable	
		Qualitative (categorical)	*Quantitative*
Independent variable	*Qualitative (categorical)*	Chi-square, logistic regression*	*t* test, ANOVA, linear regression
	Quantitative	Logistic regression*	Correlation, linear regression

*Dependent variable must be dichotomous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Independent variable	*Qualitative (categorical)*	Chi-square, logistic regression*	*t* test, ANOVA, linear regression
	Quantitative	Logistic regression*	Correlation, linear regression

*Dependent variable must be dichotomous.
ANOVA = analysis of variance.

Variables are broadly classified as qualitative (ie, categorical) or quantitative (eg, continuous) based on their scale of measurement. **Qualitative variables** (eg, type of treatment, blood type) **represent categories or groups** whereas **quantitative variables** (eg, temperature, glucose levels) **represent numerical values**. The scale of measurement of the dependent (eg, outcome) and independent (eg, exposures, risk factors) variables in a study determines the correct statistical test.

Regression analysis is used to describe the **association between 1 or more independent variables** (eg, exposures, risk factors), which may be quantitative or qualitative, and 1 quantitative dependent variable (ie, **a quantitative outcome** [eg, laboratory values]) while adjusting for other variables of interest. In this study:

- The quantitative dependent variable was serum ferritin concentration.
- The independent variables were consumption of red meat and eggs reported in ounces/week (2 quantitative variables).
- The effect of the main independent variables (eg, consumption of red meat and eggs) on the dependent variable (eg, serum ferritin concentration) is adjusted to account for the effects of other independent variables,

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a quantitative outcome [eg, laboratory values]) while adjusting for other variables of interest. In this study:

- The quantitative dependent variable was serum ferritin concentration.
- The independent variables were consumption of red meat and eggs reported in ounces/week (2 quantitative variables).
- The effect of the main independent variables (eg, consumption of red meat and eggs) on the dependent variable (eg, serum ferritin concentration) is adjusted to account for the effects of other independent variables, which are called adjustment variables (eg, age, gender). Controlling for these variables reduces the potential confounding.

Calculation of a regression line (eg, line of best fit) can then determine whether dietary consumption of red meat and eggs has a statistically significant effect on serum ferritin concentrations (after adjusting for age and gender).

(Choice A) The analysis of variance (ANOVA) test compares the mean of a quantitative variable of ≥3 independent groups. For example, it could be used in a study comparing serum ferritin concentrations (ie, quantitative variable) in children (age 0-12), adolescents (age 13-17), adults (age 18-59), and seniors (age ≥60).

(Choice B) Meta-analysis is a quantitative statistical technique used to combine and analyze data from several studies to conduct an analysis with a greater statistical power than that of the individual studies.

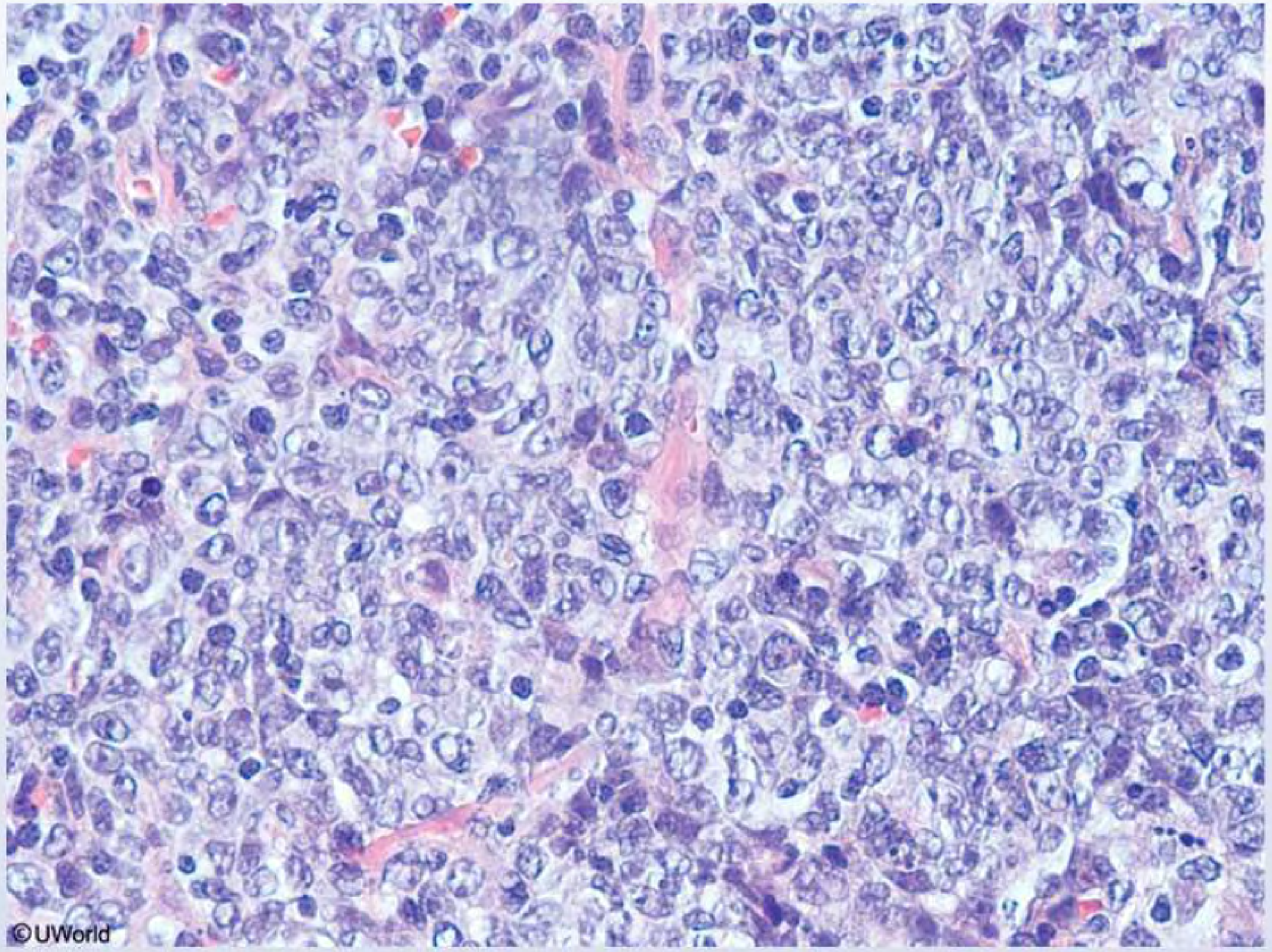
(Choices C and E) The odds ratio (OR) and the relative risk (RR) measure the strength of association between 2 categorical variables: a categorical risk factor (eg, smoker or nonsmoker) and a categorical outcome/disease (eg, presence or absence of myocardial infarction). The OR is used in case-control studies whereas the RR is used in cohort studies.

Educational objective:

A regression analysis is a statistical technique used to describe the effect that 1 or more independent variables (eg, exposures, risk factors), which may be quantitative or qualitative, can have on 1 quantitative dependent variable (ie, outcome).

References

A 13-year-old boy is admitted to the hospital due to fever and fatigue for the past week. The patient recently received a cadaveric renal transplant for glomerulonephritis, and his immunosuppressive medication regimen was increased a month ago due to early evidence of rejection. Temperature is 37.7 C (99.9 F). Heart and lung examinations are unremarkable. The liver is mildly enlarged, and the spleen tip is palpable. There is notable adenopathy of the bilateral inguinal and axillary regions. A complete blood count shows mild leukopenia. Histopathology findings from biopsy of one of the enlarged lymph nodes are shown in the image below.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Which of the following is the most likely cause of this patient's presentation?

○ A. *Aspergillus fumigatus*